AN ASSESSMENT OF ARCH DIMENSIONAL CHANGE WITH SELF-LIGATING BRACKETS: SYSTEMATIC REVIEW AND A RANDOMISED CONTROLLED TRIAL

Padhraig Seamus Fleming

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Department of Oral Growth and Development
Barts and The London School of Medicine and Dentistry
Queen Mary University of London

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DECLARATION

This thesis contains no materials that have been accepted for the award of any other degree or diploma in any university. To the best of the candidate's knowledge and belief, the thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

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ABSTRACT

The purposes of this study were to systematically review the evidence on the clinical use of self-ligating brackets (SLBs) and the validity of digital models, and to compare maxillary arch dimensional change during alignment with conventional brackets (CBs) and active or passive self-ligation in a clinical study.

In the systematic reviews, multiple databases were searched, study selection, quality assessment and data extraction were performed, and meta-analyses conducted, where appropriate. In a laboratory study a technique to measure molar inclination change incorporating digital models was developed and validated. A multicentre, 3-arm parallel-group trial was conducted with 96 patients aged 16 and above randomly allocated into 3 equal groups (Ovation^{TM}, InOvationC^{TM} or Damon Q^{TM}) and undergoing alignment with a Damon^{TM} wire sequence for at least 34 weeks.

Meta-analyses demonstrated no difference in arch dimensional changes between SLBs and CBs; however, a greater treatment time was found with self-ligation (2.2 months, 95% CI: 0.4, 3.98). The validity of direct measurement on digital models was confirmed in the other review, although meta-analysis was not possible. Complete data were obtained from 87 subjects in the trial. Bracket type had no significant effect on transverse dimensional changes with no difference in inter-molar width between passive self-ligation and CBs (0.32mm, 95% CI: -0.41, 1.05, p= 0.38) or active self-ligation (0.4mm, 95% CI: -0.31, 1.11, p= 0.27). Incisor inclination changes with Damon Q^{TM} could not be differentiated from the conventional system (0.44 degrees, 95% CI: -1.93, 2.8, p=0.71) or InOvationC^{TM} (-0.22 degrees, 95% CI: -2.58, 2.14, p=0.85).

Based on the systematic reviews, measurement of digital models is a valid alternative to plaster models, while little evidence to support the use of self-ligation was found. In the clinical trial no differences in arch dimensional changes during alignment between CBs and either active or passive self-ligation was found.

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LIST OF ABBREVIATIONS

ANCOVA: Analysis of Covariance

B-A limits: Bland and Altman limits of agreement

CB(s): Conventional bracket(s)

CBCT: Cone-Beam Computed Tomography

CCT: Controlled clinical trial

CI: Confidence Interval

CuNiTi: Copper Nickel-titanium

CT: Computerised Tomography

ICON: Index of Complexity Outcome and Need

ICW: Inter-canine width

IMW: Inter-molar width

IOTN: Index of Orthodontic Treatment Need

IPMW1: Inter-first premolar width

IPMW2: Inter-second premolar width

mm: Millimetre

Mins.: Minutes

Mn: Mandibular

Mx: Maxillary

n: Number

NHS: National Health Service

NiTi: Nickel-titanium

PA: Postero-anterior

PAR: Peer Assessment Rating

RCT: Randomised controlled trial

RME: Rapid maxillary expansion

RS: Resistance to sliding

SD: Standard Deviation

SE: Standard error

SLB(s): Self-ligating bracket(s)

SPSS: Statistical Package for the Social Sciences (Version 13)

SS: Stainless steel

SSW: Stainless steel wire

WMD: Weighted mean difference

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CHAPTER 1. INTRODUCTION.

Self-ligating brackets (SLBs) have enjoyed renewed popularity over the past decade. Many of the purported advantages of these appliances are attributed to reduced resistance to sliding within the appliance system. It is claimed that reduced resistance to sliding combined with secure arch wire ligation may influence the pattern of orthodontic alignment and levelling. However, our understanding of these interactions is largely based on anecdotal evidence, isolated case reports, retrospective studies and limited prospective research. Prospective research investigating the clinical use of SLBs has begun to emerge in recent years. However, the evidence to support the widespread use of SLBs has not been considered systematically.

The use of digital models as an alternative to plaster models in orthodontics has increased steadily, due to reduced storage requirements, rapid access to digital information, easy transfer of data, versatility and cost savings. These perceived advantages would be negated if data derived from digital models were unreliable. A systematic review of the use of digital models in orthodontics is yet to be undertaken.

An array of techniques have been tested to measure bucco-palatal orientation of teeth; the majority have involved plaster models. No single technique has met with widespread use. The use of digital models may facilitate precise and versatile, three-dimensional measurement of dental changes occurring with fixed appliance systems, although this technique requires validation.

The renaissance of self-ligating brackets has been accompanied by claims of enhanced treatment efficiency and reduced discomfort. It is believed that these appliances may be used to produce orthodontic expansion readily and simply; this property is often exploited to treat orthodontic patients without extractions. However, there is little evidence to suggest that such expansion arises, particularly in the maxillary arch. The nature of transverse expansion is also believed to have a bearing on stability. Transverse bodily movement of teeth is potentially stable, whilst expansion resulting from tipping of teeth is inherently unstable and prone to relapse. Arch dimensional changes in the maxillary arch may also have an impact on dental health and dental aesthetics. While it is accepted that the degree and nature of expansion may influence the outcome of treatment, the nature and magnitude of expansion with SLBs has not been studied. Moreover, research assessing transverse changes occurring with SLBs has not accounted for associated changes in bucco-palatal orientation, and has failed to compare changes arising with different designs of SLBs with conventional bracket designs.

CHAPTER 2. LITERATURE REVIEW.

2.1 Development of pre-adjusted edgewise appliances

Orthodontic appliances have undergone considerable changes over the last 30 years. The pre-adjusted edgewise appliance was introduced by Andrews in the 1970's, largely based on occlusal cornerstones derived from analysis of untreated ideals (Andrews, 1972; 1976). The pre-adjusted edgewise brackets were programmed to impart specific increments of tip, torque, in-out and rotational control to each tooth and reduced the need for wire bending. Numerous variations on Andrew's original prescription have been introduced over the past 30 years, although the basic principles are unchanged (Roth, 1987; McLaughlin *et al*., 2001).

Traditionally, steel or elastomeric ligatures have been used to secure the arch wire in the bracket slot, although neither system is ideal. Conventional ligation has limitations with respect to ergonomics, efficiency, plastic deformation, discoloration, plaque accumulation and friction. Self-ligating brackets have been developed and refined to address these shortcomings.

2.1.1 Self-ligating brackets

Self-ligating brackets (SLBs) are ligature-less bracket systems with a mechanical device built into the bracket to close the edgewise slot (Cacciafesta *et al*., 2003). Secure engagement may be produced by an in-built metal labial face or by a clip mechanism replacing the steel or elastomeric ligature.

Both active and passive self-ligating brackets have been developed. These terms refer to the mode in which the brackets interact with the arch wire. The active type has a spring clip that presses against the arch wire e.g. InOvation R^{TM} and InOvation C ^{TM} (GAC International, USA) and SPEED^{TM} (Strite Industries, Canada). In the passive type the clip or rigid door does not actively press against the arch wire e.g. Damon Q^{TM} (Ormco, Figure 1) and SmartClip^{TM} (3M Unitek).

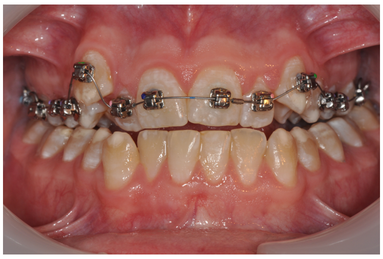


Figure 1. Damon Q™ appliance.

2.1.2 Refinement of self-ligating brackets

Use of SLBs has increased consistently and markedly in recent years; over 42 per cent of American practitioners surveyed reported using at least one system in 2008 (Keim *et al*., 2008), this figure rose from just 8.7 per cent in 2002 (Keim *et al*., 2002). Recent developments include the advent of aesthetic, ceramic variants (Figure 2, InOvation C™, GAC) and the introduction of lingual self-ligating appliances.

Figure 2. InOvation C™ brackets in the maxillary arch and mandibular anterior region.

2.2 Properties of conventional and self-ligating systems

A number of potential advantages of self-ligating appliances have been claimed including:

- More robust, secure ligation (Harradine, 2003);
- Reduced friction (Sims *et al*., 1994);
- Greater efficiency and ease of use (Maijer and Smith, 1990);
- Efficient alignment of severely irregular teeth (Harradine, 2003);
- Improved patient comfort (Shivapuja and Berger, 1994);
- Better plaque control (Shivapuja and Berger, 1994);
- Reduced overall treatment time (Harradine, 2001).

The majority of these proposed advantages have been investigated in recent years. *In* *vitro* studies have been used to investigate the impact of SLBs on wire ligation and associated frictional effects.

2.2.1 Secure ligation and full bracket engagement

The shortcomings of elastomeric materials are well documented. Taloumis *et al.* (1997) in an *in vitro* study highlighted reduction of elastomeric forces within 24 hours. Dowling *et al.* (1998) in another *in vitro* investigation into behavioural characteristics of elastomeric modules showed a 10 to 35 per cent decrease in strength after immersion in a simulated oral environment for a period of four weeks, with less reduction found for grey elastomerics than with either clear or orange variants. No pattern was found in frictional resistance with different elastomeric materials despite the decrease in force levels over the study period. These findings were supported by a further study highlighting force degradation of 73 per cent over a similar period with elastomerics; the associated frictional forces were also largely unaffected (Wong, 1976). However, the clinical relevance of these findings is debatable as the oral environment was simulated by maintaining the elastomerics at 37 degrees Celsius in a water bath (Dowling *et al*., 1998), or completely immersed at a similar temperature stretched to a length of 17mm (Wong, 1976).

Elastomerics in a figure-of-eight configuration make arch wire ligation more secure; however, this improvement is offset by an attendant increase in friction, of up to 220 per cent, with a mean increase of 65 per cent found for Minitwin™ brackets in combination with a 0.019 x 0.025 inch stainless steel wire (Sims *et al*., 1993). Self-ligating systems offer a potential solution to this problem by promoting secure ligation as full, robust engagement is assured unless the clip or slide mechanism fails (Harradine, 2003), while allowing an associated decrease in frictional resistance.

2.2.2 Reduced Friction and its clinical relevance

Friction is defined as the resistance to motion when an object moves tangentially against another. Low friction may be desirable to facilitate efficient alignment and space closure while limiting anchorage requirements. It has also been suggested that reduced friction may promote unique interactions between brackets, wires and soft tissues resulting in atypical arch dimensional changes including restraint of incisor proclination during alignment and preferential posterior arch development (Damon, 2005). This pattern of alignment has been claimed to lend itself to non-extraction based orthodontics.

Research on frictional resistance to orthodontic tooth movement *in vivo* is complex; our knowledge is almost entirely derived from laboratory-based investigations using simulated oral environments. However, it is clear that the nature of ligation has some bearing on friction within the appliance system with Schumacher *et al.* (1990) suggesting it be the primary determinant. Meling *et al.* (1997) examining the effects of friction *in vitro* concluded that each elastomeric placed in a standard configuration exerts a frictional force similar to the application of 50g tensile force to the arch wire. This study incorporated an experimental four-bracket model with vertical displacement of one premolar bracket; the effects of ageing and saliva were not assessed. Moreover, in a similar design Shivapuja and Berger (1994) reported that wire ligatures produce 30 to 50 per cent of the frictional forces of elastomerics, but that these forces still reach undesirable levels. It has also been demonstrated that placement of wire ligatures is technique-sensitive, with the force applied being very variable (Frank and Nikolai, 1980; Riley *et al*., 1979; Schumacher *et al.,* 1990; Matarese *et al*., 2008).

Attempts have been made to replicate the impact of the oral environment on the appliance system by mimicking dento-alveolar tissues, using salivary substitutes and intermittent jiggling forces similar to masticatory forces. However, it is difficult to determine the correlation between artificial set-ups and the *in vivo* situation. Furthermore, the importance of friction within orthodontic appliances *in vivo* is debated (Kusy and Whitley, 1997; Braun *et al*., 1999; Burrow, 2008). Indeed, although a reduced-friction appliance may be expected to produce more efficient alignment, rotational correction and space closure, there is a lack of published clinical evidence to support this assumption (Hain *et al*., 2003). It is also believed that high friction is occasionally preferable by limiting unwanted tooth movement, and facilitating torque delivery (Harradine, 2003; Pandis *et al*., 2006a).

A plethora of *in vitro* studies have pointed to lower friction with self-ligating systems in simulated oral environments (Shivapuja and Berger, 1994; Reicheneder *et al*., 2008; Krishnan *et al*., 2009). Passive self-ligating appliances (Damon II™, SmartClip™) typically display less friction than active systems (System R™, SPEED™) although results have been variable, reflecting inconsistencies in experimental design. Resistance to tooth movement seems to increase dramatically in self-ligating systems in regions of greater bracket displacement, corresponding to the presence of crowding in the clinical situation (Henao and Kusy, 2005).

According to Kusy and Whitley (1997), frictional resistance is only uniquely influential to tooth movement when both wire and bracket are passive and have clearance between them. However, tooth movement does not occur in a smooth progression, but rather involves a series of tipping and uprighting movements. During tipping or indeed engagement of malaligned teeth the bracket-wire interface loses passivity. In this situation, a force is exerted perpendicular to the edges of the bracket slot by the arch wire. Consequently, tooth movement *in vivo* becomes restricted by three factors: friction, elastic binding and inelastic binding or notching. Collectively these factors are known as resistance to sliding (RS). As the angle between the wire and bracket increases the relative influence of friction on tooth movement declines; at a contact angle of 7 degrees, just 6 to 7 per cent of RS with NiTi or stainless steel arch wires can be attributed to friction (Articolo and Kusy, 1999).

In the crowded dentition resistance to sliding is vastly increased; the effects of crowding can be mimicked in laboratory set-ups. Read-Ward *et al.* (1997) reported that the reduction in resistance to sliding with self-ligating systems is lessened when the wire is active. SPEED™ brackets in particular produced little RS in round wires; resistance to sliding increased greatly with rectangular wires. Measurements were undertaken predominantly in the dry state, however, with saliva used only in conjunction with aligned brackets. A further study by Loftus *et al*. (1999) with a simulated periodontal ligament involving silicone material injected into an acrylic model, with slight tip and rotation of the brackets to mimic the effects of relatively minor malalignment, determined that sliding resistance with Damon SL™ was not significantly lower than with conventional ligation. While this study was the first to attempt simulation of the periodontal ligament in the assessment of frictional resistance, it involved just one bracket, which does not reflect clinical practice.

Thorstenson and Kusy (2002a, b) also assessed variation in tip on the resistance to sliding, to mimic the influence of crowding. They found that angulation beyond the critical contact angle of 6 degrees causes an exponential rise in frictional resistance for both self-ligating (Damon SL™) and conventional brackets, although lower levels of RS were typical of Damon™ brackets. At an angulation of 6 degrees mesial with a 0.018 x 0.025 inch stainless steel wire, this difference (60 cN) was considered to be of clinical significance. These findings allied to those of Henao and Kusy (2005) underline the reduction in RS associated with self-ligating systems, while suggesting that differences may be less marked than those reported in many other *in vitro* investigations. These studies both relied on drawing an archwire through a two-bracket set-up with an inter-bracket distance of 18mm; this situation also differs markedly from that encountered clinically. Using a similar design with vertical bracket displacement, Cordasco *et al.* (2009) found significantly lower frictional forces with passive self-ligation than conventional systems, although the experimental model was limited to a three-bracket design.

Masticatory activity may reduce impediments to tooth movement during orthodontic treatment with fixed appliances. In a further *in vitro* analysis, repeated vibrations simulating the masticatory cycle were delivered, while the frictional resistance was measured using an Instron^{TM} universal testing machine (O' Reilly *et al*., 1999). The authors reported a reduction in friction of up to 85 per cent with simulated masticatory forces and concluded that the importance of friction in orthodontic appliances is overstated, given the likelihood of bracket or arch wire displacements under masticatory forces *in vivo*. This study was based on a three-bracket model, which is quite distinct from the clinical situation. The assessment of frictional forces was also undertaken directly after the vibratory cycles; this approach may therefore have amplified the influence of masticatory activity on friction. Similar conclusions were made by Iwasaki *et al.* (2003) in a clinical study involving a conventional appliance. Vibration induced by mastication reduced but failed to eliminate resistance to sliding. While the latter study was carried out *in vivo*, the sample was limited to two subjects. A supplementary vertical force was necessary during space closure to facilitate the experimental set-up, and measurements were taken directly after chewing gum for 3 to 5 minutes; the design may therefore also be unrepresentative of the clinical situation.

While the influence of friction on the rate of tooth movement remains unresolved, more recently *ex vivo* research has begun to focus on the effects of a reduced-friction system on force levels in simulated malocclusions and on the resultant pattern of orthodontic alignment. Baccetti *et al*. (2011) in a comparison of alignment forces with apically- and buccally-displaced canines reported similar residual forces for alignment with conventional brackets, low-friction ligatures and passive self-ligation at mild to moderate levels of displacement. However, with severe displacement (6mm), force levels on the displaced canines dissipated with conventional brackets suggesting that low friction systems may be of greater value in severely crowded cases. This analysis was restricted to recording force levels on the target tooth only with changes on either adjacent or non-adjacent teeth not considered; directional forces were also not evaluated.

Fok *et al*. (2011) using a state-of-the-art orthodontic simulator attempted to quantify the three-dimensional effects of alignment of a maxillary canine vertically-displaced by 4mm from the maxillary arch with both passive self-ligation (Damon MX^{TM}) and elastomeric ligation. The authors reported significantly higher force levels on the canine with conventional elastomerics; they argue that these high force levels are in excess of those needed for effective tooth movement. Furthermore, undesirable, high force levels were detected on adjacent teeth with conventional systems; forces were also shown to propagate throughout the arch with conventional ligation but were confined to neighbouring teeth only with self-ligation. It is suggested that passive self-ligation will therefore result in less undesirable movement of adjacent teeth than is the case with conventional ligation. The authors also highlight that maxillary incisor proclination is a likely consequence of alignment of a vertically-displaced canine with conventional systems (Fok *et al*., 2011). The apparatus used in this study, however, was funded by the developer of the passive self-ligation system.

On the basis of the available evidence, Harradine (2003) concluded that self-ligation provides a very significant reduction in friction in all dimensions of tooth movement. The author reports that self-ligating systems enable a tooth to “slide along an arch wire with lower and more predictable net forces, while maintaining complete control, with almost none of the undesirable rotation of the tooth resulting from a deformable mode of ligation”. More recently, further assumptions have been made in respect of the effects of a low friction system on arch dimensional changes. The clinical evidence relating to these assertions are considered in detail in Chapter 4.

2.2.3 Efficiency and ease of use of self-ligating brackets

Self-ligation results in a modest saving in chair-side time when compared to conventional appliances (Table 1). Authors have suggested this saving could be used to schedule more patients; increase efficiency; improve patient relations; or allow oral hygiene reinforcement (Maijer and Smith, 1990).

Table 1. Reported time savings with self-ligating compared with conventional systems

Study	Self- ligating system(s)	Conventional mode of ligation	Time saving
Maijer and Smith (1990)	SPEED^{TM}	Elastomerics	7 mins.
Shivapuja and Berger (1994)	Activa^{TM}, Edgelok^{TM}, SPEED^{TM}	Wire ligatures	12 mins.
	Activa^{TM}, Edgelok^{TM}, SPEED^{TM}	Elastomerics	1 min.
Voudouris (1997)	Interactwin^{TM}	Elastomerics	2.5 mins.
Berger and Byloff (2001)	SPEED^{TM}	Elastomerics	2 to 3 mins.
Harradine (2001)	Damon SL^{TM}	Elastomerics	25 seconds
Turnbull and Birnie (2007)	Damon 2^{TM}	Elastomerics	1.5 mins.

Clinical research studies investigating the remaining purported advantages of the use of self-ligating brackets had not previously been the subject of systematic review. These properties are, therefore, reviewed systematically in Chapter 4.

2.3 Factors influencing orthodontic arch development

The dentition is thought to lie in a position of muscular balance or equilibrium supported by the periodontal ligament, alveolar bone, and the attached and unattached gingivae (Weinstein, 1967; Proffit, 1978). Resting soft tissue pressures as well as metabolic activity within the periodontal membrane are primary determinants of tooth position and arch form (Proffit, 1978; Moss, 1980). Secondary factors, including head posture, facial type, jaw and tongue posture, crown morphology and alteration of the eruptive mechanisms may modify these primary determinants. Disruption of the forces maintaining teeth in a normal relationship by overcoming the resistance of the periodontal ligament, alveolar bone and gingivae, may result in planned tooth movement as well as unplanned tooth migration.

Orthodontic treatment may involve alteration of arch form, arch dimensions and arch length. Some degree of arch form and dimensional change invariably occurs during treatment (Weinberg and Sadowsky, 1996). In a prospective trial, AlQabandi *et al*. (1999) demonstrated that non-extraction treatment is likely to result in significant unintentional lower incisor proclination and inter-canine expansion during alignment with both rectangular and round wires. A positive correlation between the degree of crowding and proclination was shown; an inverse relationship between inter-canine expansion and labial segment proclination was also reported. However, it was not possible to pinpoint the cause of incisor proclination as the mean depth of the Curve of Spee was up to 4.2mm. This study was also reported as a randomised controlled trial but lacked detail regarding randomisation procedures and had uneven numbers in both treatment groups.

2.4 Arch dimensional changes with growth

Our knowledge of characteristic growth-related changes in arch dimensions is based largely on longitudinal analyses of reference models, while retrospective follow-up studies form the mainstay of our understanding of treatment-related changes together with their implications on long-term stability. Intra-arch occlusal changes may be gauged by measuring specific dimensions including inter-canine, inter-premolar and inter-molar widths, arch length, arch circumference and dental irregularity. Dental inclination changes may also be charted using serial radiographs or sequential model measurement.

The dental arches undergo characteristic changes as they grow, adapt and age. Cephalometric data have confirmed that changes in the craniofacial skeleton continue throughout life (Forsberg, 1979; Behrents, 1984; Fudalej *et al*., 2007). These are mirrored in the dental arches being most marked in the first two decades, although minor alterations continue well into adulthood. A plethora of studies have considered normative dental arch dimensional changes arising during childhood and adolescence (Barrow and White, 1952; Dockrell *et al*., 1952; Moorrees and Reed, 1965). Less attention has been given to dental changes arising during early adulthood and beyond.

DeKock (1972) assessed arch dimensional changes in Caucasians of northern European ancestry between 12 and 26 years. Gender-independent reductions in arch depth occurred throughout the second and third decades. Transverse dimensions changed little, although a small statistically significant increase in arch width arose in males between 12 and 15 years.

Sinclair and Little (1983) evaluated dental casts of 65 untreated normal occlusions to determine the nature and extent of maturational changes on the normal dentition. Six dental parameters were examined in the mixed dentition (9 to 10 years), early permanent dentition (12 to 13 years), and early adulthood (19 to 20 years). Decreases arose in arch length and inter-canine width with minimal overall changes in inter-molar width, overjet and overbite, and increases in lower incisor irregularity. More marked changes occurred in females, with the individual changes being variable and unpredictable.

Bishara *et al*. (1998) reported a long-term follow up of arch dimensional changes over a 45-year period. Subjects were drawn from two pools of normal individuals, with one group being evaluated longitudinally at 6 weeks, 1 year, and 2 years. Fifteen males and 15 females from the Iowa Growth Study were also evaluated at six intervals over a period of up to 45 years. Arch length continued to increase until 13 years in the maxillary arch, but only until 8 in the mandibular arch. Thereafter significant and consistent decreases occurred in both arches mesial to the first molars. Between 13 and 45 years mandibular arch length reduced by 5mm in both male and female groups (Bishara *et al*., 1998).

Carter and McNamara (1998) conducted a longitudinal analysis of dental changes arising in 53 untreated individuals between late adolescence and the fifth or sixth decade of life. Inter-canine widths decreased significantly in both genders with a greater change observed in the mandibular arch. Minor changes occurred in the maxillary arch dimensions (Table 2). The sample was generally representative, although Class III malocclusion was not considered.

Table 2. Reductions in transverse dimensions (mm) between 17 and 48 years. (Carter and McNamara, 1998). Data are presented as Mean (SD).

Dimension	Maxillary ICW	Maxillary IPMW	Maxillary IPMW2	Maxillary IMW
Male	0.76 (0.55)	0.22 (0.8)	0.04 (0.77)	0.12 (0.8)
Female	0.65 (0.72)	0.35 (0.61)	0.23 (0.82)	0.22 (0.66)

Insignificant change in maxillary inter-molar and inter-second premolar width was also demonstrated in both females and males (Carter and McNamara, 1998). This finding indicates that both maxillary inter-second premolar and inter-molar width is stable in untreated subjects from 17 to 48 years of age. Furthermore, the rate of change is very gradual occurring at a maximum of 0.025mm per year for maxillary inter-canine width. However, if the subjects had previous orthodontics, the maxillary inter-molar width decreased significantly over the 30-year post-treatment period, although the rate of the change was also slow. All of these studies were observational in design with the majority of the data obtained from longitudinal growth studies including the Iowa (Bishara *et al*., 1998) and Michigan (Carter and McNamara, 1998) growth studies, and are therefore susceptible to selection and information bias. Nevertheless, it is reasonable to suggest that arch dimensional changes occurring after 16 years are likely to be relatively minor and gradual.

2.5 Effect of growth on dental inclination changes

The bucco-lingual inclination of the dentition is controlled by apical position, and skeletal and soft tissue influences. Inclination changes have been assessed using cephalometric data and information derived from serial reference models. Temporal change in molar inclination has been measured either by gauging long axis orientation (Janson *et al*., 2004) or by relating inclination changes to the occlusal surfaces (Ross *et al*., 1990). There is, however, a paucity of research investigating longitudinal changes in the axial inclination of the dentition.

Variations in inclination are believed to arise with differing vertical skeletal relationships. Increased lower anterior face height coincides with posterior crowns with greater buccal inclination and longer functional lingual cusps. Conversely, reduced lower anterior face height is associated with more pronounced lingual inclination of the posterior teeth and longer buccal cusps (Isaacson *et al*., 1971; Schudy, 1963; Schendel *et al*., 1976; Fish *et al*., 1978). However, this relationship has been questioned with Ross *et al*. (1990) finding no statistical differences in molar inclination between facial types. Conversely, Janson *et al*. (2004) confirmed the relationship with respect to the maxillary arch but failed to find a similar association in the mandibular arch. These observed differences may stem from the use of different reference planes to assess inclination in the latter two studies.

Temporal changes in dental inclination have been assessed in cross-sectional research of adolescents (13 to 15 years) and adults (16 to 26 years) using a 3-dimensional electromagnetic digitizer (Ferrario *et al.*, 2001). An age-related uprighting of all teeth with the exception of maxillary incisors from adolescence to young adulthood was reported. A mean change of 0.9 to 6.9 degrees in maxillary first molar inclination was found in males, with roots more placed further buccally in adulthood. The findings of this study, however, may be questioned in view of the cross-sectional design. Age-related differences may have been confounded by individual differences and secular trends, although the age difference between the groups in this study was less than 10 years. Subjects were, however, derived from the same region and were of white Caucasian ethnicity.

In summary, there is little evidence relating to longitudinal changes in dental inclination. However, it appears that changes are minor with changes of less than one degree annually during adolescence being representative; little alteration seems to develop after 16 years (Ferrario *et al.*, 2001).

2.6 Arch dimensional changes with orthodontic treatment

While specific mechanics can predictably produce desired expansion, subtle arch form and dimensional changes also occur with conventional edgewise mechanics, irrespective of the extraction protocol (Weinberg and Sadowsky, 1996). Alignment of crowded arches treated without extractions, tooth size reduction or active distal movement occurs by an increase in arch perimeter produced by arch expansion and proclination. Extraction spaces may be used to facilitate alignment in crowded extraction cases; however, slight expansion of inter-canine dimension is also typical in these cases. Retrospective studies form the mainstay of our knowledge of such changes.

Paquette *et al.* (1992) examined 63 subjects with a borderline need for extractions. The treatment-related increase of the maxillary inter-canine width in those treated with extraction therapy was 0.8mm; the corresponding increase in the non-extraction sample was almost identical (0.9mm). In the same sample the maxillary inter-molar width increased by 2.8mm in the 30 subjects treated without extraction, while this dimension was almost unchanged in those treated with extractions. Luppanapornlarp and Johnston (1993) in a 15-year follow-up of 62 patients reported minimal expansion of just 0.9mm and 1.7mm in the maxillary inter-canine and inter-molar widths, respectively during the treatment phase in the 29 patients treated without extraction. However, the pre-existing tooth size-arch length discrepancy in the mandibular arch in both studies was less than 1mm. Consequently, in these cases treated without extraction minimal change in transverse arch dimensions is an expected finding.

2.7 Effect of fixed appliance treatment on incisor inclination changes

Inadvertent mandibular incisor proclination may arise following relief of dental crowding (Weinberg and Sadowsky, 1996; AlQabandi *et al*., 1999). In a retrospective study of 30 Class I subjects treated on a non-extraction basis where lower incisor advancement was unplanned, Weinberg and Sadowsky (1996) noted mean advancement of the lower incisors of 2.1mm with proclination of 6.1 degrees occurring. This study involved a range of treatment modalities; for example, tandem mechanics involving Class III elastic wear were used in eight patients; this is likely to have masked the effects of relief of crowding on sagittal movement of the incisors.

There is a premium on the maintenance of ideal torque in the upper labial segment following removal of maxillary premolars, in particular. Yoshida *et al.* (2001) have demonstrated moments arising during retraction of the maxillary incisors culminating in loss of torque and uprighting. Excessive 'slop' or 'play' between the archwire and bracket slot and low modulus of elasticity of bracket and wire materials exacerbate this problem (Gioka and Eliades, 2004). Recently, prospective studies concerning incisor advancement and transverse changes occurring with fixed appliances have been published (See 2.8).

2.7.1 Effect of fixed appliance treatment on buccal segment inclination changes

Traditionally, transverse expansion in non-growing individuals is achieved with fixed orthodontic appliances in isolation e.g. quadhelix, rapid maxillary expansion (RME) or pre-adjusted edgewise appliances, or in combination with surgery. A relatively simple alternative used by some clinicians involves use of self-ligating brackets in conjunction with expanded nickel-titanium archwires, which is claimed to result in preferential expansion in the posterior regions (Harradine, 2009); this expansion may be harnessed to limit the requirement for extractions (Prettyman *et al*., 2012). However, little is known in relation to the efficacy, nature and expedience of this approach.

Researchers have demonstrated that expansion usually develops due to a combination of bodily movement and dental tipping; tipping movements are thought to predominate with the quadhelix appliance (Frank and Engel, 1982). Handelman (1997) suggested that stable expansion may be achieved in adults with average inter-molar increases of 4.6mm and inter-premolar increases of 5.5mm retained almost six years following cessation of retention with only three degrees of buccal molar tipping remaining bilaterally. This finding suggests that tipping movements may be unstable while bodily changes may persist in the long-term. However, this study was retrospective in design. In all subjects RME was also followed by fixed appliances, potentially nullifying the tipping movements arising with rapid maxillary expansion.

Kilic *et al.* (2008) in a prospective comparison of bonded and banded rapid palatal expanders reported a mean inter-molar increase of 7.66mm with the banded Hyrax appliance. This was accompanied by tipping of up to 18.1 degrees of the first molar; the mean amount of tipping was 9.5 degrees. A novel measurement technique involving digitisation of radiographs of plaster models was used in this study; this approach was based on the height of buccal and palatal cusps tips, therefore being sensitive to longitudinal changes due to occlusal wear. However, the measurement technique was shown to have high repeatability.

Using spiral Computerised Tomography (CT), Garib *et al.* (2005) demonstrated buccal tipping of premolars and molars as a result of rapid palatal expansion; the maxillary second premolars underwent the greatest mean degree of tipping of up to 7.5 degrees. In a similar study involving repeated Cone Beam Computed Tomography (CBCT) of 30 adolescent patients, Garrett *et al.* (2008) highlighted that expansion was evenly divided between skeletal and dental changes. Alveolar bending accounted for 6 per cent of total expansion at the maxillary first premolars and 13 per cent at the first molars. True dental tipping was responsible for 39, 46 and 49 per cent of the expansion at the first premolars, second premolars and first molars, respectively. While these studies involved detailed assessment, longitudinal use of CT scans carries attendant incident radiation, it is therefore unlikely that ethical approval would be granted for research of this nature in the United Kingdom.

To date, inclination changes arising secondary to transverse dimensional changes with conventionally-ligated pre-adjusted edgewise appliances in isolation has not been investigated.

2.8 Effect of treatment with SLBs on arch dimensions and inclination changes

Among the claims made by the manufacturers of SLBs is the facility for significant transverse expansion contingent on an altered response to soft tissue pressures. It is proposed that light applied forces allow the lips to compete with and overcome the tendency to advance the incisors during alignment (Harradine, 2009). Consequently, orthodontists in America have reported being statistically more likely to treat crowded malocclusions without extractions when using SLBs than would be the case with CBs (Prettyman *et al*., 2012). At present, there is little evidence to support this practice. Furthermore, the mechanism of expansion with SLBs remains unclear; expanded titanium alloy archwires are recommended for use with the Damon™ system. Consequently, expansion may be related to archwire form rather than bracket type.

It is accepted that while conventional ligation can apply a high labio-lingual force, incomplete archwire engagement may also arise. The effective 'play' between archwire and bracket walls is high with an attendant reduction in torque delivery, highlighted in clinical research by a lack of difference in subjective aesthetic outcomes with use of varying torque prescriptions anteriorly (Moesi *et al.,* 2013). Torque delivery with SLBs is believed to vary pending on the mode of archwire engagement. An active self-ligation clip has been shown to express torque at a lower 'slop' angle than a passive bracket. A reduction in the effective 'slop' of 7 degrees with a 0.019" x 0.025" wire with InOvation™ brackets was highlighted (Badawi *et al.,* 2008). These findings were supported by a further laboratory investigation (Huang *et al*., 2009); this difference may be clinically relevant.

Furthermore, *in vitro* scrutiny has shown that passive SLBs may also be significantly over-sized further compromising torque expression (Cash *et al*., 2004). This property may be particularly relevant as torque delivery is influenced by archwire play both in the tooth or segment of teeth under torsional forces and also in neighbouring teeth (Huang *et al*., 2009). Nevertheless, clinical studies are required to confirm the significance of these findings.

Franchi *et al.* (2006) in a prospective follow-up of 20 patients treated with fixed appliances with low friction ligatures reported significant transverse increases in the maxillary arch during the initial 6 months of appliance therapy. Mean expansion of 1.71 to 3.65mm was demonstrated for maxillary transverse dimensions with increases peaking in the premolar region. Inter-molar expansion of 1.71mm was related to both bodily movement and tipping with 4.33 degrees of buccal flaring observed. However, this study is of limited value as it lacked a control group undergoing treatment with either conventional ligation or self-ligating brackets.

More recently, prospective comparisons of arch dimensional changes occurring with self-ligating and conventional pre-adjusted edgewise appliances have been published (Table 3). These studies are appraised systematically in Chapter 4. However, it is apparent that inclination changes with self-ligating brackets have not yet considered the buccal segments. Further research investigating potential differences in the pattern of arch alignment related to bracket-type is therefore required.

Table 3. Prospective studies comparing mandibular arch changes and incisor inclination changes with SLBs and CBs.

Clinical trial	**N**	**ICW change (mm)**	**IPMW1 change (mm)**	**IPMW2 change (mm)**	**IMW change (mm)**	**Incisor inclination change**
Scott *et al*. (2008a)	60	0.11	-	-	0.72	-0.64
Pandis *et al*. (2007)	54	-0.5	-	-	1.61*	0.19
Fleming *et al*. (2009a)	60	-0.32	-0.73	-0.29	0.91*	0.09
Pandis *et al*. (2010a)^	54	-0.2	-	-	1.4*	-2.5

Positive values represent more expansion or proclination with SLBs.

* $p < .05$

^This study was a follow-up of earlier findings reported by Pandis *et al*. (2007)

2.9 Effect of arch dimension and inclination changes on periodontal support

Ackerman and Proffit (1997) have suggested that the dentition is limited antero-posteriorly and transversely by skeletal substructures and soft tissue influences. In addition to concerns pertaining to stability, violation of the anatomic limits set by the cortical plates may accelerate iatrogenic sequelae such as alveolar bone resorption, fenestration, root resorption, and gingival recession (Wainwright, 1973; Ten Hoeve and Mulie, 1976). It has been postulated that gingival recession may develop secondary to alveolar bone dehiscence resulting from expansion. Areas denuded of bone may undergo rapid gingival recession until a normal distance is established between the base of the pocket and the crestal bone, establishing a structure more resistant to further progression (Årtun and Krogstad, 1987).

Early research on animal models has implicated excessive arch dimensional changes on such unwanted periodontal effects (Steiner *et al*., 1981). Steiner *et al*. (1981) examined the effects of 3.05mm of labial movement of the mandibular incisors on five Macaca *nemistrina* monkeys. Following exploratory surgery, significant gingival recession, and apical migration of the connective tissue and marginal bone was discovered. Research on autopsy material has also implicated pronounced sagittal incisor movement, in the presence of a narrow and high symphysis, in progressive bone loss of the lingual and labial cortical plates (Wehrbein *et al*., 1996). A thin alveolus may be a feature of any skeletal type, but is most frequently encountered in patients with increased lower face height and skeletal Class III patterns (Handelman, 1996; Chung *et al*., 2008; Gracco *et al*., 2009). Individuals with these facial patterns may, therefore, be more prone to iatrogenic periodontal defects during treatment.

Allais and Melsen (2003) compared cohorts of treated and untreated subjects. Cephalograms were analysed to ascertain the degree of incisor proclination developing during treatment; these changes were related to gingival recession measured on reference models. The authors reported that minimal lengthening of the clinical crown (0.12mm) was typical. However, significant recession was noted in some instances; this was less likely in those with good oral hygiene and thick gingival biotype. Further research involving clinical measurement of periodontal support has demonstrated a weak association between expansion or proclination and loss of periodontal support (Ruf *et al*., 1998; Djeu *et al*., 2002; Melsen and Allais, 2005; Bassarelli *et al*., 2005). In addition, clinical inspection of subjects having undergone incisor proclination almost eight years previously has also not revealed deterioration in periodontal support following appliance removal (Årtun and Grobety, 2001). These negative findings may, however, relate to the measurement technique. Assessment of alveolar bone loss from intra-oral radiographs is unreliable particularly in the anterior region; crowding, rotations and excessive angulation may complicate identification of the cemento-enamel junction and alveolar crest. These studies were also retrospective in design relying on study models to assess the magnitude of recession; baseline recording of periodontal attachment was also unfeasible.

Contemporaneous research in this area has become increasingly sophisticated with the advent of Computerised Tomography (CT) scanning (Kim *et al*., 2009). Kim *et al*., (2009) in a cross-sectional study assessed periodontal and alveolar bone integrity in the anterior region following orthodontic preparation for surgical correction of skeletal III deformity. Up to 8mm of bone loss at the mandibular lingual plate was recorded, equating to denudation of over 75 per cent of the root length. On average, the maxillary incisors had alveolar bone covering over 70 per cent of their root length on both labial and lingual aspects; the corresponding figure was 40 per cent for the mandibular incisors. Furthermore, the horizontal bone thickness at the apex was only 2.13mm lingual to the mandibular incisors. However, given the cross-sectional nature of the study, the amount and type of incisor movement during pre-surgical orthodontic treatment was not measured and could not be related to differences in bone levels. In addition, scans were taken following orthodontic decompensation only; consequently, it was unclear whether reduced bone levels and thickness were pre-existing, exacerbated by treatment, or solely iatrogenic.

2.10 High quality research evidence for orthodontic practice.

Ismail and Bader (2004) have defined evidence-based dentistry (EBD) "as an unbiased approach to oral health care that follows a process of systematically collecting and analyzing scientific evidence with the objective of gaining useful decision making information with minimal bias." Current principles of evidence-based practice require an expert for quick and correct identification of the underlying condition, the use of the best available evidence, and consideration of patient choice and preference. Although important discoveries have emerged from low quality evidence, the results from studies of high quality have a greater bearing on decision-making, as there are fewer associated risks (Straus *et al.*, 2007). High quality meta-analyses and systematic reviews, and randomised controlled trials (RCTs) of low risk of bias constitute the higher levels of evidence.

It is generally agreed that orthodontic practice should be underpinned by best available evidence ensuring patients undergo treatment proven to be safe, effective and efficient. Despite widespread acceptance of evidence-based approaches, a limited knowledge of evidence sources, including the Cochrane database, low utility of evidence portals including PubMed, and inadequate knowledge of scientific terms is commonplace among practicing orthodontists (Madhavji *et al.*, 2011). It is therefore unsurprising, as is true of many aspects of dentistry and medicine, that clinical progress and planning decisions in orthodontics have outpaced the underlying research base. In particular, the use of self-ligating brackets has become an accepted form of treatment with a lack of convincing evidence to underpin many of the proposed benefits of SLBs.

A randomised controlled trial (RCT) is a preplanned experiment to assess the effects, benefits or safety of at least one treatment modality. RCTs use a control group and randomisation to assign participants to treatment arms, and aim to create similar treatment groups in all respects other than the intervention, with any observed differences between treatment groups arising due to chance. High quality RCTs should form the basis of systematic reviews of treatment interventions.

Systematic reviews are undertaken to assimilate the available evidence in a systematic, transparent and unbiased manner and, where applicable, to pool results from individual trials. Information identified in systematic reviews may be combined qualitatively, or quantitatively in a meta-analysis. Meta-analyses produce more precise estimates of the efficacy and safety of a therapy compared to individual studies. The results of systematic reviews may help to resolve existing controversies regarding therapies and inform future trials.

Systematic reviews remain prone to problems including selective study inclusion (selection bias), publication bias, and inclusion of studies of variable quality or design (Higgins *et al.*, 2011; Jüni *et al.*, 2001). However, narrative reviews have been superseded by systematic reviews as narrative approaches lack systematic and transparent search methods, involve unstructured inclusion and appraisal of included studies, and may have subjective data synthesis. Prior to this research project, there had been no published systematic review of the evidence on the use of SLBs.

2.11 Measurement of tooth movement

Orthodontic treatment involves complex and often indeterminate tooth movement with resultant alteration in intra- and inter-arch relationships. Traditionally, dental changes have been assessed using two-dimensional linear measurements from gypsum reference models or radiographic images. However, tooth movement is a complex phenomenon occurring in three spatial planes. The specific pattern of movement particularly transverse changes and inclination changes has implications for clinical outcomes, facial and dental aesthetics, and the long-term stability of treatment. The development and refinement of three-dimensional imaging modalities has raised the possibility of a deeper understanding of the pattern and chronology of changes arising due to treatment.

2.12 Measurement of tooth movement in two dimensions

Traditionally, orthodontic tooth movement has been gauged clinically but measured using two-dimensional techniques, including cephalometric and panoramic radiographs, and reference models. Disadvantages of the use of dental radiographs of any kind include exposure to ionising radiation, inherent limitations related to validity and reproducibility, and limited scope for measurement of dental changes. Study models may be used to provide two-dimensional or three-dimensional information pending on the measurement tool used. Increasingly, clinicians are espousing plasterless, virtual models to eliminate problems and costs related to plaster storage. Consequently, two-dimensional methods are progressively being superseded by three-dimensional techniques.

2.12.1 Radiographs: Lateral cephalograms

Baumrind and Frantz (1971) highlighted errors of projection, errors of identification and measurement errors in cephalometry. Projection errors arise because radiographs are produced from x-rays within a divergent beam, producing a two-dimensional shadow of a three-dimensional object. Enlargement may occur depending on the plane on which an estimated point lies; foreshortening of distances between points in different planes may also develop. Anatomic landmarks each have variable, non-circular envelopes of error. Landmarks on a gradual curve e.g. gonion and condylion, rather than an edge or a sharp fold are particularly difficult to identify accurately (Adenwalla *et al*., 1988). The assessment of changes in mandibular incisor inclination is complicated by identification of the apex of the mandibular incisor (Baumrind and Frantz, 1971;

Midtgard *et al.*, 1974; Phelps and Masri, 2000).

Furthermore, dental measurements from a single cephalogram are typically limited to assessment of the inclination of the maxillary and mandibular incisors to their respective dental bases; measurement of tooth orientation in the buccal segments is unreliable. Nevertheless, researchers have also attempted to estimate mesio-distal movement of the buccal segments from cephalograms with acceptable levels of agreement both with teeth in occlusion (Benson *et al.*, 2007) and apart (Sugawara *et al.*, 2006). However, measurement of bucco-lingual inclination changes of the posterior dentition is impossible on a lateral view but has been evaluated on postero-anterior (PA) radiographs (Hicks, 1978; Asanza *et al.*, 1997; Byloff and Mossaz, 2004).

2.12.2 Superimposition of lateral cephalograms

To negate the influence of growth and maturation in the assessment of treatment changes over an extended time period, superimposition on stable reference structures has traditionally been used in orthodontics. No single cephalometric superimposition technique has gained widespread acceptance with a variety in use. In relation to the mandibular dentition, Björk's structures for assessment of growth and treatment changes are commonly used (Björk and Skieller, 1983). However, superimposition on the mandibular outline has been shown to be more reliable particularly where the interval between serial radiographs is under 12 months (Cook and Southall, 1989). Regional superimposition of the maxillary arch has been accomplished using various structures, planes and registration points including: Björk's key ridge; palatal vault; Pancherz analysis (Pancherz, 1984; Feldmann and Bondemark, 2008); and Johnston's pitchfork analysis.

Each technique is considered to be of limited validity and reproducibility. Consequently, the use of exogenous implants has been developed as a research tool to highlight changes arising with growth (Bjork and Skieller, 1983). Reproducibility remains problematic when used in conjunction with cephalograms; moreover, this technique is also reliant on a surgical procedure that may not be sanctioned by ethical review committees unless the implant was the focus of the research. Repeated cephalograms are also reliant on ionising radiation and superimposition risks introducing further inaccuracy (Houston and Lee, 1985).

2.12.3 Panoramic radiographs

Comparison of pre-treatment and near of end of treatment panoramic views permits assessment of mesio-distal tooth positioning and root parallelism. Panoramic views have also been advocated to grade the quality of orthodontic outcome (Casko *et al*., 1998; Isaacson *et al*., 2008). However, evidence to support the use of repeated panoramic views is limited and “unlikely to be indicated except for patients with severe malocclusions” (Isaacson *et al*., 2008). In particular, Owens and Johal (2008) demonstrated that panoramic views produce clinically acceptable representation of mesio-distal root angulation in just 27 per cent of cases. Greatest inaccuracy develops in the canine-premolar region in both arches. This finding is in keeping with those of McKee *et al*. (2002), Philipp and Hurst (1978), and Samawi and Burke (1984).

Further problems associated with the panoramic view include:

- Lack of sharpness, due to various factors including ghost imaging, summation images, static distortion and processing errors
- Horizontal distortion; this tends to be nonlinear (Tronje, 1981)
- Vertical distortion, which is more pronounced than horizontal distortion (Rowse, 1971)
- Superimposition of the cervical spine
- Limited focal trough; lingually-positioned roots falling outside the focal trough are usually magnified (Leach *et al.,* 2001). Similarly, excessively inclined teeth not contained within the boundaries of the focal trough may appear narrow or foreshortened. Consequently, the anterior region of the panoramic view may be unrepresentative; reliability may be complicated further by inaccurate patient positioning within the machine.

2.12.4 Linear study model measurement

Dental changes have been assessed in two dimensions using direct measurement on reference models. This technique has been used to quantify changes occurring with growth and maturation (Barrow and White, 1952; Moorrees and Reed, 1965; DeKock, 1972; Sinclair and Little, 1983; Harris, 1987; Bishara *et al.*, 1998), as a consequence of fixed orthodontic appliance therapy (Paquette, 1992; Luppanapornlarp and Johnston, 1993; Weinberg and Sadowsky, 1996; Vaden *et al*., 1997; Yavari *et al*., 2000; Isik *et al.,* 2005; Pandis *et al*., 2007; Scott *et al*., 2008a), and following removal of orthodontic appliances to analyse stability and relapse (Little *et al*., 1981; Uhde *et al*., 1983; Sadowsky *et al*. 1994). These measurements tend to be reproducible but fail to account for inclination changes that are an inevitable consequence of appliance therapy.

2.13 Three-dimensional measurement and Cone Beam Computed Tomography (CBCT)

The ultimate aim of three-dimensional imaging and modelling is to develop the 'virtual orthodontic patient', where bone, soft tissue and teeth can be recreated in three dimensions (Hajeer *et al*., 2004). The panacea of complete three-dimensional digital representation has been prompted by the advent of Cone Beam Computed Tomography (CBCT), the refinement of three-dimensional facial scanning and photography, and the development of digital study models.

Computerised Tomography (CT) and in particular CBCT has raised the possibility of accurate three-dimensional radiographic information at little biologic cost. Unlike the fan-shaped X-ray beam used in conventional Computerised Tomography, CBCT uses a cone-shaped beam to record projection data via a flat detector, during a single 360^o rotation. Cone Beam Computed Tomography is capable of higher spatial resolution than conventional CT, with isotropic voxels as small as $0.125mm^3$. Scanning time is comparable to that of state-of-the-art conventional CT (10 to 40 seconds). However, although the radiation dosage encountered in a typical CBCT scan remains higher than in conventional radiographic imaging, it is significantly lower than dosages associated with conventional CT (Silva *et al*., 2008).

Volumetric data are reconstructed using algorithms similar to those used in conventional CT. As with conventional CT, data can be used to create multi-planar and three-dimensional reconstructions. CBCT units are generally smaller and cheaper than conventional CT scanners. Comparisons of measurement of craniofacial landmarks using CBCT and direct assessment with digital calipers have confirmed the validity of the technique as a measuring tool (Periago *et al*., 2008; Brown *et al*., 2009).

Thick multi-planar, perspective or orthogonal reconstructions of CBCT scans can be used to produce lateral and frontal cephalometric images without distortion or magnification for orthodontic assessment (Grauer *et al*., 2010; van Vlijmen *et al*., 2009;

Cattaneo *et al*., 2008; Kumar *et al*., 2007). Projection errors are not considered a major source of variability for linear and most angular measurements (Kumar *et al*., 2008). Landmark identification has also been found to be easier with synthetic cephalograms derived from CBCT due to more pronounced contrast (Grauer *et al*., 2010). Consistency between measurements generated from a CBCT scan with actual measurements on a skull have been confirmed with the NewTom 3G^{TM} (Lascala *et al*., 2004) with readings marginally smaller with CBCT images. In a further study, skulls were scanned with i-CAT ^{TM} and compared with the anatomic truth and with various plain-film radiographic images (Hilgers *et al*., 2005). With the exception of some outliers, the 3D radiographic reconstructions provided accurate and reliable linear measurements.

Further applications of CBCT include quantification of tooth position and bone volume (Gracco *et al*., 2009), and assessment of root length and volumetric changes in periodontal support structures (Kim *et al*., 2009; Lund *et al*., 2010). In addition, Cone-beam CT has been applied as a means of digital model production without the need for taking impressions and subsequent pouring or scanning of these impressions (Kau *et al*., 2010; Baumgaertel *et al*., 2009). Mean discrepancies between CBCT-derived models and OrthoCad^{TM} digital software of just 0.03mm, 0.2mm and 0.14mm were reported for overbite, overjet and Little's irregularity index, respectively (Kau *et al*., 2010).

2.14 Three-dimensional measurement of tooth movement

A variety of tools have been tested to facilitate measurement of tooth movement including an optical profilometer, travelling microscope and laser hologram inferometry (Wedendal and Bjelkhagen, 1974). However, these techniques are largely obsolete having been replaced chiefly by laser scanners.

Laser scanners were piloted by Yamamoto *et al*. (1991) who used a triangulation method registering on the centroid of the occlusal surface of each tooth to facilitate superimposition. Measurements were undertaken on a relatively small sample (10 patients) over periods of 41 to 190 days demonstrating error of 0.1mm for translation and 0.5 degrees for rotational movements. The authors failed to carry out any reliability assessment.

Soma *et al*. (1992) used a slit-ray projector and CCD video cameras to generate up to 200 three-dimensional spatial co-ordinates on a line 30mm in length. Digitisation of a model required over eight minutes. The authors failed to describe the accuracy or reproducibility of the technique. Thereafter, Kuroda *et al*. (1996) introduced a similar system capable of generating 90,000 sets of X, Y and Z coordinates per cast. They reported a measurement error of less than 0.05mm, illustrated validity with respect to vernier caliper measurement, and harnessed the technique for clinical purposes soon after (Motohashi and Kuroda, 1999; Okumura *et al*., 1999).

Ashmore *et al*. (2002) used digital superimposition techniques to compare three-dimensional changes in molar position occurring with and without headgear treatment in Class II division 1 malocclusion. Superimposition was performed registering specific points on the palatal rugae with a desktop mechanical digitizer (Microscribe 3DX^{TM}), which collects three-dimensional data through a stylus tip placed on the point being captured. A LabVIEW^{TM} software program was used to read the serial port communications from the digitizer and computed the X, Y, and Z coordinate locations of the stylus tip. Procrustes superimposition of four molar points allowed assessment of changes in tooth position. The average translation of the centroid between the repeated measurements ranged from 0.02 to 0.05mm (SD: 0.28 to 0.41mm). Although variation reached up to 1.78mm, differences were not found to be of statistical significance using a paired t-test. However, the reliability of the method for computing rotation of maxillary molars was poor with large standard deviations detected (7 to 11 degrees). In their assessment, the authors also failed to distinguish between changes occurring on individual molars.

Matching algorithms were also used by Keilig *et al*. (2003) in an analysis of 20 dental models. Measurement of translational movements was accurate to 0.4mm with rotational accuracy to within just 1 degree reported. Statistical tests to assess either the validity or reproducibility of these differences were not reported. Cha *et al*. (2007) confirmed the validity of the INUS^{TM} dental scanning solution used in conjunction with Rapidform^{TM} software to measurements obtained from cephalometric superimposition ($p > 0.05$). The standard error was 0.029mm (SD: 0.158mm). However, this study could be criticised as the authors failed to test the reproducibility of the laser scanning technique and used cephalometry as a gold standard despite its recognised limitations.

Also using Rapidform^{TM} software, Thiruvenkatachari *et al*. (2009) demonstrated high levels of agreement between information generated on digital models and direct measurement in an experimental model using digital calipers. A mean difference of 0.06mm in inter-molar width was demonstrated between the techniques although a range of almost 2mm was noted. Similarly, the scanner was accurate to 0.024mm for anteroposterior movements and to 0.007mm for buccopalatal movements. These findings were supported by a clinical comparison of this technique against data derived from lateral cephalometric views, although the significance of this finding is questionable in view of the difficulty in assessing movement of maxillary molars cephalometrically without use of exogenous markers on subjects with teeth in occlusion. In recent years, research on laser scanning techniques has led to the development of proprietary digital study models capable of providing accurate three-dimensional occlusal information.

2.15 Superimposition on stable palatal structures

The potential for assessment of dental changes using superimposition on the palatal rugae has existed for many years. The shape of the palatal vault and the medial portions of the palatal rugae are relatively stable throughout the development of the dentition retaining their shape and pattern throughout life (Lebret, 1962); consequently, they may be used for identification purposes in forensics. From 5 years of age to adulthood, the rugae increase in length by an average of 2mm (Lysell, 1955).

Research findings investigating the validity of superimposition techniques have been equivocal; however, this approach remains the most widely used in orthodontics. Peavy and Kendrick (1967) demonstrated that the lateral aspects of the palatine rugae were unstable being influenced by tooth movement in the sagittal plane. The rugae, however, were found to be unaffected by transverse changes. They concluded that the lateral rugae were of limited benefit in mapping alterations in tooth position.

Similarly, van der Linden (1978) highlighted instability of the rugae in conjunction with sagittal orthodontic tooth movement. The author carried out a longitudinal assessment of 6 orthodontically treated children and 65 untreated children between 6 and 16 years. A mean change of 0.41mm in the antero-posterior position of the rugae was found. More significant changes at both the medial and lateral rugae points were found in the treated groups.

In a sample of subjects with Class II malocclusions, Almeida *et al.* (1995) highlighted that the medial points of the second and third rugae were stable reference points for longitudinal cast analysis. The lateral rugae were less stable undergoing changes in both the treatment and control groups. Similarly, in a longitudinal analysis over a four-year period, Christou and Kiliaridis (2008) demonstrated that the third rugae may be a reliable reference to assess longitudinal dental changes. Less significant vertical displacements in the position of the rugae were found in adults than in adolescents.

Despite the observed changes in palatal anatomy arising in conjunction with orthodontic treatment, palatal superimposition compares favourably with radiographic superimposition techniques. Hoggan and Sadowsky (2001), in a longitudinal retrospective study, found no statistical difference between incisor movement measured cephalometrically and using palatal rugae. They concluded that the palatal rugae are as reliable as cephalometric superimpositions to assess antero-posterior molar movements. A limitation of this research is that the recognised gold standard is itself of questionable validity with respect to measurement of tooth movement.

In a study involving first premolar extractions and labial segment retraction with temporary anchorage devices as stable landmarks, Jang *et al.* (2009) found that the lateral points of the palatal rugae displaced more than the medial points of the palatal rugae. In addition, the third rugae showed the least displacement. While the methodology used in this study was sound, temporary anchorage devices are known to undergo micromovement and changes in position particularly during loading (El-Beialy *et al*., 2009). Consequently, some of the observed displacements may be related to inaccurate registration. Similar results were observed by Bailey *et al* (1996) who suggested that the amount of tooth movement affects the stability of the palatal rugae. Treatment involving premolar extraction also produced changes in the positions of the lateral points of the first palatal rugae. The latter samples were also confined to subjects undergoing incisor retraction. It is likely that different and less significant changes in palatal topography may be observed with other tooth movements.

2.16 Measurement of dental inclination changes on plaster models

Dental inclination changes have been measured on plaster models in both the buccal and labial segments in a variety of ways. A major limitation of the assessment of methods used to gauge inclination changes is the absence of a true gold standard. Radiographic methods to measure incisor inclination record the most prominent incisor with apical position being masked by superimposition and lack of clarity of adjacent incisor roots. Furthermore, a discrepancy may arise due to inconsistent orientation of crown and root. Therefore, while amalgamation of study models and lateral (Bennett and Smales, 1969; Perera, 1981) and PA (Oliveira *et al*., 2004) cephalograms has been attempted, many techniques are independent of radiographs. Experimental techniques reported in the literature include:

- Direct measurement on study models (Handelman, 1997; Handelman *et al*., 2000; Huynh *et al*., 2009);
- Use of torque gauges in the buccal segments (da Silva Filho *et al*., 1991; Northway and Meade, 1997; Ciambotti *et al*., 2001; Chung and Goldman, 2003);
- Torque gauges in the incisor region (Richmond *et al*., 1998);
- Digital imaging of radiographic images of stone models (Oktay and Kilic, 2007)
- Tracing of transverse palatal contours using a symmetrograph (Ciambotti *et al*., 2001). The inclination of the molars was measured using steel projections from silicone caps;
- Measuring the height of the disto-buccal and disto-lingual tips of molars with a dial calliper (Northway and Meade, 1997);
- Using a combination of three-dimensional digitisation and trigonometry (Bassarelli *et al*., 2005);
- Taking laser photocopies of trimmed models (Chung and Goldman, 2003);
- Photographs of trimmed models (Iseri and Özsoy, 2004);
- Three-dimensional assessment techniques and contour tracers (Lear, 1976; Richmond, 1987);
- Digital measurement of molar inclination constructed by intersecting tangents to the mesiobuccal and mesiolingual cusp tips bilaterally (Franchi *et al*., 2006);
- PA cephalograms (Defraia *et al*., 2008);
- PA cephalograms in conjunction with intra-oral tantalum implant markers in human subjects (Hicks, 1978);
- PA cephalograms in conjunction with acrylic caps and metal struts on maxillary first

molars (Ramoglu and Sari, 2010);

- PA cephalograms in conjunction with extra-oral tantalum implant markers in Macaca mulatta (Cotton, 1978).

These techniques are either two-dimensional or are performed directly on plaster models or non-proprietary reconstructed models. Use of digital models to measure inclination of the buccal segments has only been applied crudely for American Board of Orthodontics scoring. Furthermore, those researchers had difficulty applying the ABO method of measuring inclination in the buccal segments to digital models (Costalos *et al*., 2005; Okunami *et al*., 2007). To date there has been no refined use of digital models to measure inclination changes.

2.17 Digital study models

Study models have traditionally been held in the form of physical plaster models, which are subject to loss, fracture and degradation. Digital storage eliminates problems related to physical storage of models with up to $17m^3$ of space required for storage of traditional models for one thousand patients (McGuinness and Stephens, 1992). The replacement of plaster orthodontic models with virtual information has further potential benefits including instant accessibility of three-dimensional information; the ability to perform accurate and simple diagnostic setups of various extraction patterns; virtual images may also be transferred anywhere in the world for instant referral or consultation.

Digital study models were introduced commercially in 1999 by OrthoCad™ (Cadent, Carlstadt, NJ) and refined in 2001 (emodels™, GeoDigm, Chanhassen, Minn). The technology used to generate digital study model scanning varies considerably. Emodels™ involves scanning the surface of a complete plaster model, whereas the earlier techniques relied on “destructive scanning” with multiple scans of a model undertaken in thin slices.

The potential advantages of digital models for the quantification of orthodontic problems would be negated if the validity, efficiency, and ease of linear and angular measurement of occlusal features with digital models were not comparable to that related to plaster models, the current ‘gold standard’ used routinely in clinical practice.

CHAPTER 3. AIMS, OBJECTIVES AND OVERVIEW OF METHODOLOGY

3.1 Research Problems

Conventional pre-adjusted edgewise appliances have been used for over 30 years to predictably produce orthodontic alignment. However, aggressive marketing and claims of superior clinical performance have led to widespread adoption of self-ligating brackets (SLBs). SLBs are proposed to produce more efficient alignment of crowded teeth with reduced friction between bracket and archwire resulting in more rapid and predictable tooth movement. They are also claimed to facilitate orthodontic expansion permitting non-extraction orthodontic treatment. Prospective research investigating the clinical use of SLBs has emerged in recent years. However, the evidence to support the widespread use of SLBs has not been evaluated systematically.

The use of digital models as an alternative to plaster models in orthodontics has increased steadily, being prompted by reduced storage requirements; rapid access to digital information; easy transfer of data; versatility; and financial savings. These perceived advantages would be nullified if digital conversion of occlusal information resulted in poor reliability of the resultant data. A systematic review of the use of digital models in orthodontics has not previously been carried out.

An array of techniques have been tested to measure the bucco-palatal orientation of teeth; the majority have involved plaster models. No single technique has met with widespread use. The use of digital models may facilitate precise and versatile, three-dimensional measurement of dental changes occurring with fixed appliance systems, although this technique requires validation.

Transverse bodily movement of teeth is potentially stable; expansion resulting from tipping of teeth is inherently unstable and prone to relapse following removal of appliances. While it is accepted that the degree and nature of expansion may have a significant bearing on the outcome of treatment, the nature and magnitude of expansion with SLBs has not been studied. Moreover, research assessing the impact of SLBs on transverse changes has not accounted for changes in bucco-palatal orientation concomitant with transverse increases, and has failed to consider changes arising with different designs of SLBs with respect to conventional bracket designs.

3.2 Aims and Objectives

The aims of the current research include a systematic appraisal of the use of SLBs and digital models in orthodontics and to quantify the nature and magnitude of expansion induced by SLBs and conventional brackets (CBs). To facilitate this, a novel measurement technique to assess three-dimensional changes in tooth position was to be piloted.

Objectives:

1. To systematically review the evidence relating to the clinical use of SLBs during orthodontic treatment
2. To systematically review the validity of measurement of digital study models for use in orthodontics
3. To pilot a novel technique for measuring dental inclination changes
4. To investigate the influence of appliance type on dental inclination changes and arch dimensional changes in a randomised controlled trial. The null hypothesis to be tested was that treatment with three different fixed appliance systems would result in no difference in transverse dimensions or dental inclination changes during levelling and alignment.

3.3 Overview of methodology

1. Evidence relating to orthodontic treatment with CBs and SLBs was to be reviewed systematically. Outcome measures included: Arch dimensional changes; measures of treatment of efficiency including alignment efficiency, rate of orthodontic space closure, and overall treatment time; pain experience; risk of bond failure; and periodontal effects related to both SLB and CB systems. Electronic databases were to be searched with no restrictions relating to publication status or language of publication. Study selection, quality assessment and data extraction were to be performed in duplicate, and meta-analyses were to be conducted, where appropriate.

2. The validity of measurement of occlusal features on digital models was also to be assessed systematically including: tooth size; transverse dimensions, irregularity index; arch width; crowding; Bolton ratio; occlusal indices and inter-arch occlusal features. Studies comparing linear and angular measurements obtained on digital and

standard plaster models were to be identified by searching multiple databases including MEDLINE, LILACS, BBO, ClinicalTrials.gov, the National Research Register and Pro-Quest Dissertation Abstracts and Thesis Database. Items from the Quality Assessment of Studies of Diagnostic Accuracy included in Systematic Reviews checklist (Whiting *et al*., 2003) were to be used to assess the methodological quality of included studies.

3. A laboratory-based validation study was to be carried out on 20 sets of pre- and post-treatment models. Dental inclination changes were to be measured in three dimensions using a novel measurement technique. Sequential reference models were to be captured and measured using a three-dimensional laser scanner (3Shape™, Copenhagen, Denmark). Subsequently, this measurement technique was to be applied on data derived from the clinical trial.

4. A multi-centre randomised controlled trial with three parallel groups was to be carried out at Barts and The London NHS Trust, Kent and Canterbury Hospital and Southend NHS Trust. Adult patients from the treatment waiting lists requiring upper arch fixed appliance therapy on a non-extraction basis were to be recruited.

Subjects were to be randomly allocated to one of three groups using a computer-generated sequence. The groups were to be treated with Damon Q™, InOvation C™, or Ovation™ brackets following a pre-determined 'Damon' archwire sequence for a minimum of 34 weeks after placement of the pre-adjusted appliances at which stage a 0.019 X 0.025 inch stainless steel archwire would be engaged and expressed fully. The main outcome measure was the difference between the transverse maxillary dimensional changes (inter-canine; inter-premolar and inter-molar widths) arising during alignment and levelling with the three appliance systems.

CHAPTER 4. A SYSTEMATIC REVIEW OF THE CLINICAL USE OF SELF-LIGATING BRACKETS IN ORTHODONTICS.

4.1 Objectives

The purpose of this systematic review is to evaluate the clinically significant effects of self-ligating brackets (SLBs) on orthodontic treatment with respect to the quality of scientific evidence and the methodology of those reports. An understanding of clinical evidence on the impact of SLBs on orthodontic treatment would inform the orthodontist's decisions in relation to their choice of fixed appliance system.

4.2 Materials and Methods

To be included in the review, trials had to meet the following selection criteria:

Study design: Randomised (RCTs) and controlled clinical trials (CCTs).

Participants: Patients with full arch fixed orthodontic appliance(s) treated with SLBs and metal conventional brackets (CBs).

Interventions: Fixed appliance orthodontic treatment involving SLBs or CBs.

Outcome measures: Arch dimensional changes; measures of treatment of efficiency including alignment efficiency, rate of orthodontic space closure, and overall treatment time; pain experience; risk of bond failure; and periodontal effects related to both SLB and CB systems.

Search Strategy for Identification of Studies

The following electronic databases were searched in April 2009 initially forming the basis of the initial review (Appendix 1); searches were updated in January, 2013: MEDLINE via OVID (1950 to January 2013, Appendix 2), EMBASE (1980 to January 2013), the Cochrane Central Register of Controlled Trials (The Cochrane Library, 2013). Language restrictions were not applied. Unpublished or 'grey' literature was searched using ClinicalTrials.gov (www.clinicaltrials.gov) and the National Research Register (www.controlled-trials.com) using the term 'orthodontic and bracket'. Authors were contacted to identify unpublished or ongoing clinical trials and to clarify data as required. Reference lists of the included studies were screened for relevant research.

Assessment of Relevance, Validity, and Data Extraction

All assessments including analysis of research for inclusion in the review, risk of bias assessment and extraction of data were performed independently and in duplicate by two investigators (PSF and Ama Johal). The investigators were not blinded to the authors or the results of the research. Disagreements were resolved by joint discussion. Seven criteria were considered to grade the risk of bias inherent in individual studies: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of assessors; incomplete outcome data; selective reporting of outcomes; and other potential sources of bias. Each individual outcome was scored as at low, unclear or high risk of bias. An overall assessment of risk of bias (high, unclear, low) was also made for each included trial using the Cochrane Collaboration risk of bias tool. Studies with one or more criterion adjudged to be at high risk of bias were considered to be at high risk of bias overall and excluded from the meta-analysis.

Data Synthesis

A data extraction form was developed to record study design, observation period, participants, interventions, outcomes, and outcome data of interest. A data extraction form was used to tabulate data on the outcomes of interest including continuous outcomes such as alignment efficiency and transverse changes, and dichotomous outcomes including attachment failures. Pain intensity using a visual analog scale (VAS) was obtained at all available time intervals. Pain scores assessed by means other than a zero to 100 VAS were to be equated with this scale by multiplying the original scale by an appropriate factor.

Clinical heterogeneity of included trials was gauged by assessing the participants and methodology of primary studies particularly setting, treatment protocol, materials used, timing of data collection and measurement techniques. Statistical heterogeneity was to be assessed by inspecting a graphical display of the estimated treatment effects from the trials with emphasis on the overlap of 95% confidence intervals. The Chi^2 test was to be used to assess for heterogeneity, a p-value below 0.1 signifying significant heterogeneity. I^2 tests for homogeneity were to be undertaken to quantify the extent of heterogeneity prior to each meta-analysis. I^2 values above 50% would signify moderate to high heterogeneity, which may preclude meta-analysis.

Meta-analysis would be carried out if there were sufficient similarities between studies in respect of types of participants, interventions and outcomes. A weighted treatment effect was to be calculated and the results expressed as mean differences and 95% confidence intervals (CI) for continuous outcomes and odds ratios and 95% CI for dichotomous outcomes. In general random-effects models were to be used for meta-analyses. If more than ten studies were included in meta-analysis, standard funnel plots and contoured enhanced funnel plots were to be drawn to assess publication bias.

Sensitivity analysis

Sensitivity analyses were planned at the outset to address differences between studies at low and unclear risk of bias, publication bias and other potential sources of heterogeneity including overriding effects of large studies. Meta-analyses and sensitivity analyses were to be undertaken in STATA version 12.1™ (STATA Corporation, College Station, USA) using 'metan' and 'metareg' commands.

Quality of evidence (GRADE)

The quality of evidence was to be assessed using GRADE with GRADE evidence profile tables produced (Guyatt *et al*., 2011). The GRADE system is used to assess the overall body of evidence initially assuming high level of evidence from RCTs, but downgrading as appropriate based on the following domains: a) study limitations (Risk of Bias); b) inconsistency of results; c) indirectness of evidence; d) imprecision of results; e) publication bias. The quality of evidence was to be classified as follows:

- High: Further research is very unlikely to change our confidence in the estimate of effect
- Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- Very Low: Any estimate of effect is very uncertain

4.3 Results

Search Results/Study selection

Forty-six trials were initially deemed potentially relevant to the removal of seven duplicate reports; forty-four were identified from either MEDLINE via OVID or the Cochrane Central Register of Controlled Trials, one study from a conference abstract (Wong *et al*., 2012) and a further unpublished trial from contact with researchers (Brock, 2008). After analysis of the abstracts and de-duplication 34 articles remained. Following detailed assessment of potentially relevant full-text articles (Figure 3), four studies were excluded (Table 5) and 30 studies were considered relevant for inclusion. Therefore, thirteen additional relevant reports were identified in the updated search (January, 2013).

Table 4. Yield from electronic searches prior to removal of duplicates.

Database	Keywords	Results	Full articles retrieved	Articles selected
MEDLINE via OVID (1950 to January 2013)	See Appendix 2.	84	36	22
Cochrane Central Register of Controlled Trials (January 2013)	Self-ligating or Self-ligation	28	17	16
LILACS (1982 to 2013)	Self-ligating AND orthodontic	12	0	0
BBO (1982 to 2013)	Self-ligating AND orthodontic	9	0	0
ClinicalTrials.gov (January 2013)	orthodontic and bracket	0	0	0
National Research Register (January 2013)	orthodontic and bracket	0	0	0

Table 5. List of excluded full-text articles (n=4) with reasons for exclusion.

Article	Reason excluded
Jiang and Fu (2008)	Observational study.
Miles and Weyant (2010)	Used ceramic conventional bracket as control.
Cattaneo *et al.* (2011)	RCT of two SLB systems not involving conventional control group.
Chapman (2011)	RCT of two SLB systems not involving conventional control group.

Description of studies (Table 6)

Of the 30 studies considered relevant for inclusion, fourteen were RCTs and the remaining 16 were CCTs. There were five split-mouth studies (Miles *et al*., 2006; Pandis *et al*. 2006b; Miles, 2007; Pellegrini *et al*., 2009; Buck *et al*., 2011); twenty-five had parallel group designs, two of which involved three groups (Brock, 2008; Wong *et al*., 2012). The majority of studies concerned passive SLBs, although active SLBs were considered in four reports, with InOvation R^{TM} considered in three studies (Pandis *et al*., 2008a; Pellegrini *et al*., 2009; Buck *et al*., 2011) and Time 2^{TM} in a further randomised trial (Johansson and Lundstrom, 2012).

Outcomes assessed included: dimensional changes during orthodontic alignment, alleviation of irregularity using Little's irregularity index, the rate of orthodontic space closure, overall treatment time and number of required visits, subjective pain experience recorded using visual analogue scales, plaque retention, the extent of root resorption developing during treatment, and attachment debond failures related to either appliance system.

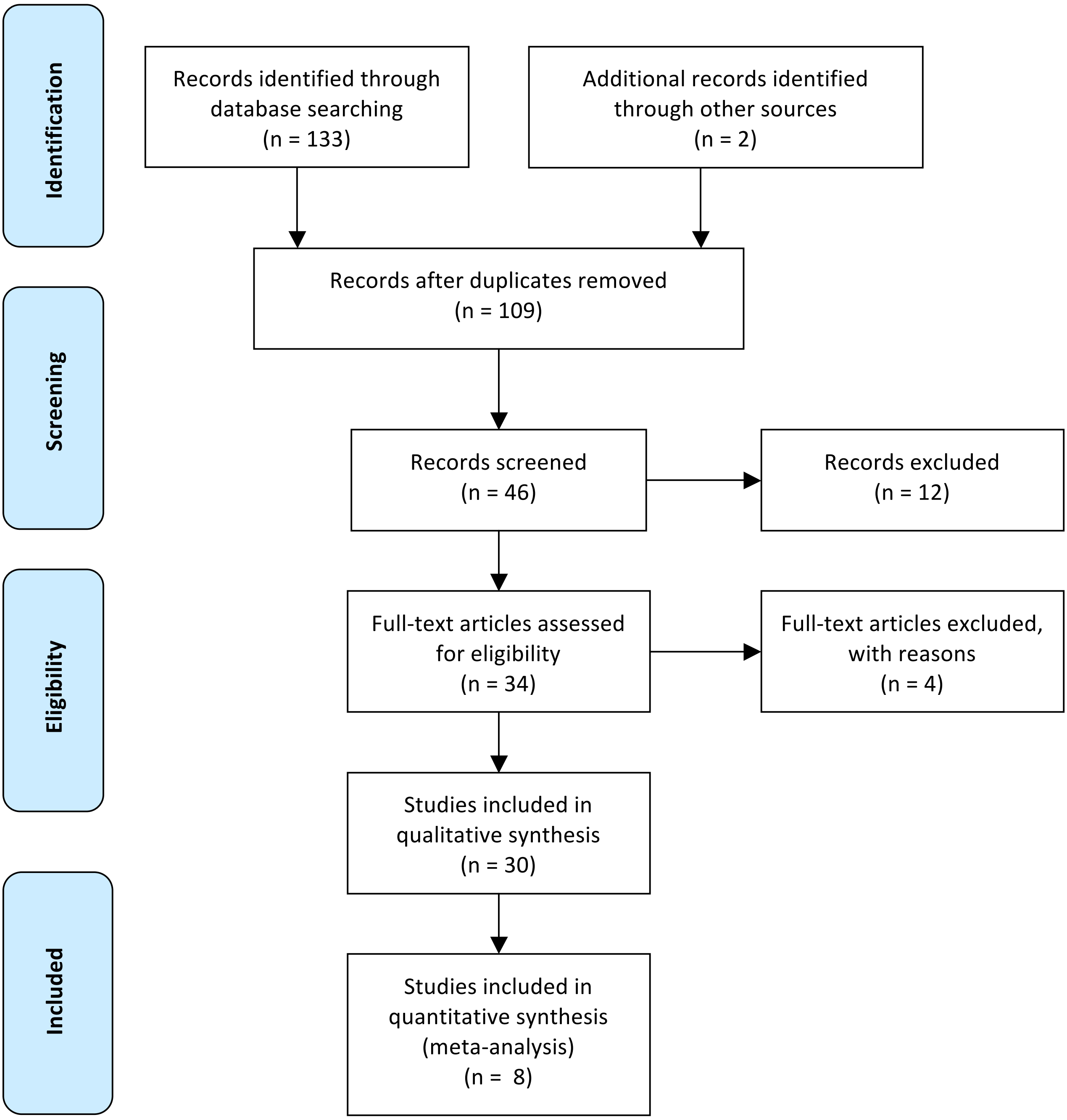


Figure 3. PRISMA diagram of article retrieval.

Table 6. Summary of characteristics of included reports (n=30).

Study	Methods	Participants	Interventions	Outcomes
Miles (2005)	CCT, Observed at 10 and 20 weeks	48 patients. Mean age 17.1 years, 26 male, 32 female	Group 1: 24 patients with SmartClip^{TM} Group 2: 24 patients with Victory^{TM}	- Rate of initial alignment lower 3-3
Miles *et al.* (2006)	CCT, split-mouth design, Observed at 10 and 20 weeks	58 consecutive patients. Mean age 16.3 years, 18 male, 40 female	Lower appliance with Damon II^{TM} or Victory^{TM} brackets in alternate quadrants	- Rate of initial alignment lower 3-3 - Pain experienced at chairside and following appliance manipulation - Bracket failure rate recorded
Pandis *et al.* (2006a)	CCT, Observed following orthodontic alignment	105 patients. Mean age 16.14 (2.9) years, 36 male, 69 female	Group 1: 52 patients with Damon II^{TM} Group 2: 53 patients with Microarch^{TM}	- Change in inclination of U1 to SN and NA lines during treatment
Pandis *et al.* (2006b)	CCT, split-mouth.	62 patients. Mean age 14 years, 23 male, 39 female	Group 1: 43 patients with Damon II^{TM} Group 2: 19 patients with Microarch^{TM}. Appliances were bonded with Transbond Plus^{TM} and Transbond XT^{TM} or OrthoSolo^{TM} and Enlight^{TM}	- Bracket failure rate over a 12 month period

Miles (2007)	CCT, split-mouth. Observed at 5 weekly intervals during space closure	13 patients analysed. Median age 13.1 years, 5 male, 8 female	Clarity™ appliance placed upper 3-3 with SmartClip™ or Victory™ bracket on 2nd premolars	Rate of orthodontic space closure
Pandis *et al*. (2007)	CCT, Observed until alignment achieved	54 patients. Mean age 13.7 (1.38) years, 11 male, 43 female	Group 1: 27 patients with Damon II™ Group 2: 27 patients with Microarch™	-Time taken (days) to align lower 3-3
Brock (2008)	CCT, Observed for 7 days following appliance placement	44 patients. Age range 11-20 years, 15 male, 29 female	Group 1: 12 arches with Tip-Edge™ Group 2: 16 arches with Victory™ Group 3: 16 arches with Damon MX™	- Daily subjective pain experience for 7 days following appliance placement - Analgesic consumption
Pandis *et al*. (2008a)	CCT, Periodontal examination before and after orthodontic treatment	100 patients. Age range 12-17 years, 36 male, 64 female	Group 1: 50 patients with InOvation R™ Group 2: 50 patients with Microarch™	- Plaque, gingival and calculus indices, and probing depth for mesial, buccal and distal aspects of mandibular 3-3.
Pandis *et al*. (2008b)	CCT, Observed following orthodontic treatment	96 patients. Mean age 13.21 (1.64) years, 29 male, 67 female	Group 1: 48 patients with Damon II™ Group 2: 48 patients with Microarch™	Root length before and after treatment on panoramic radiographs
Scott *et al*. (2008a)	RCT, Observed at 8 weeks and following mandibular alignment	62 patients recruited. Mean age 16.27 (4.47) years, 32 male, 30 female	Group 1: 33 patients with Damon MX™ Group 2: 29 patients with Synthesis™	- Rate of initial alignment lower 3-3 - Time taken (days) to align lower arch in 0.019 X 0.025” SSW -Root shortening of mandibular incisors

Scott *et al*. (2008b)	RCT, Observed for 1 week following appliance placement	62 patients recruited. Mean age 16.27 (4.47) years, 32 male, 30 female	Group 1: 33 patients with Damon MX™ Group 2: 29 patients with Synthesis™	- Subjective pain experience at 4 hours, 24 hours, 3 days and 7 days following appliance placement - Analgesic consumption
Fleming *et al*. (2009a)	RCT, Observed at 30 weeks following appliance placement	60 patients. Mean age 16.35 (2.73) years, 21 male, 39 female	Group 1: 29 patients with SmartClip™ Group 2: 31 patients with Victory™	- Transverse dimensional change - Incisor inclination change
Fleming *et al*. (2009b)	RCT, Observed for 1 week following appliance placement and at chairside	48 of 66 patients analysed. Mean age 15.96 (2.56) years, 16 male, 32 female	Group 1: 26 patients with SmartClip™ Group 2: 22 patients with Victory™	- Subjective pain experience at 4 hours, 24 hours, 3 days and 7 days following appliance placement - Analgesic consumption - Pain experience at chairside
Fleming *et al*. (2009c)	RCT, Observed at 8 weeks	65 patients. Mean age 16.28 (2.68) years, 22 male, 43 female	Group 1: 32 patients with SmartClip™ Group 2: 33 patients with Victory™	- Rate of initial alignment lower 6-6
Pellegrini *et al*. (2009)	CCT, split-mouth. Observed 1 and 5 weeks after appliance placement	18 patients. Mean age 13.9 years, 5 male and 13 female	InOvation R™ or MiniOvation™ brackets on alternate lateral incisors	- Mean bacterial counts - ATP-driven bioluminescence determinations
Pringle *et al*. (2009)	RCT, Observed for 8 days following appliance placement	52 of 66 patients analysed. Mean age: TruStraight 16.1 (7.4) years, Damon3 15.2 (6.8). 24 male, 28 female	Group 1: 28 patients with TruStraight™ Group 2: 24 patients with Damon MX™	- Subjective pain experience at 2 time intervals on 8 consecutive days following appliance placement

Tecco *et al*. (2009a)	CCT, Observed over initial 3 months of alignment	30 patients. Mean age 16.8 years, 12 male, 18 female	Group 1: 15 patients with Damon II™ Group 2: 15 patients with Victory™	- Daily subjective pain experience and analgesic use over initial 3 months of appliance therapy
Tecco *et al*. (2009b)	CCT, Observed over initial 12 months of treatment	40 patients. Age range 14 to 30 years, 12 male, 18 female	Group 1: 20 patients with Damon II™ Group 2: 20 patients with Victory™	- Transverse dimensional change
Fleming *et al*. (2010)	RCT, Followed for duration of treatment	54 patients. Mean age 15.8 years, 18 male, 36 female.	Group 1: 28 patients with SmartClip™ Group 2: 26 patients with Victory™	- Treatment duration - Occlusal improvement
Ong *et al*. (2010)	CCT, Observed at 10 and 20 weeks	50 patients. Age range 10-18 years, 20 male, 30 female	Group 1: 44 arches with Damon MX™ Group 2: 40 arches with Victory™ (n= 22) or MiniDiamond™ (n= 18)	- Rate of initial alignment upper and lower 3-3
Pandis *et al*. (2010a)	CCT, Observed following orthodontic treatment	54 patients. Mean age 13.8 (1.5) years, 11 male, 43 female	Group 1: 27 patients with Damon II™ Group 2: 27 patients with Microarch™	-Transverse dimensional change - Incisor inclination change
Pandis *et al*. (2010b)	CCT. Observed 87 days after appliance placement	32 patients. Mean age 13.6 (1.5) years, 16 male and 16 female	Group 1: 16 patients with Damon II™ Group 2: 16 patients with Microarch™	- Streptococcus mutans counts
Buck *et al*. (2011)	CCT, split-mouth. Observed at 12 months	54 patients. Mean age 13.9 years, 4 male, 9 female	InOvation R™ or MiniOvation™ brackets on alternate lateral incisors	- Mean bacterial counts, ATP-driven bioluminescence determinations and demineralisation

DiBiase *et al*. (2011)	RCT, Followed for duration of treatment	48 patients. Up to 30 years.	Group 1: 27 patients with Damon MX^{TM} Group 2: 21 patients with Synthesis^{TM}	- Treatment duration - Occlusal improvement
Pandis *et al*. (2011)	RCT, Observed when 0.016 X 0.025" NiTi passively engaged	50 patients. Mean age 13.3 (1.6) years, 17 male, 33 female	Group 1: 25 patients with Damon MX^{TM} Group 2: 25 patients with Microarch^{TM}	- Transverse dimensional change - Time to alignment
Gaspar-Ribeiro *et al*. (2012)	RCT, Observed at 180 days and 600 days	19 patients. 7 male, 12 female	Group 1: 10 patients with EasyClip^{TM} Group 2: 9 patients with Victory^{TM}	- Rate of initial alignment lower 6-6
Johansson and Lundstrom (2012)	RCT, Followed for duration of treatment	90 patients. Age range 11.7-18.2 years, 26 male, 64 female.	Group 1: 44 patients with Time2^{TM} Group 2: 46 patients with Gemini^{TM}	- Treatment duration - Occlusal improvement
Wahab *et al*. (2012)	RCT, Observed at 1, 2, 3 and 4 months	29 patients. Age range 14-30 years, 10 male, 19 female	Group 1: 14 patients with Damon MX^{TM} Group 2: 15 patients with MiniDiamond^{TM}	- Rate of initial alignment upper 3-3
Wong *et al.* (2012)	RCT, Observed for 3 months during space closure	40 patients. Age range 12-16 years, 10 male, 19 female	Group 1: 13 arches with CBs Group 2: 13 arches with CBs and SuperSlick^{TM} ligatures Group 3: 14 arches with Damon MX^{TM}	- Rate of space closure
Pejda *et al.* (2013)	RCT, Observed at 6, 12 and 18 weeks	38 patients. Mean age 14.6 (2.0) years, 13 male, 25 female	Group 1: 19 arches with Damon MX^{TM} Group 2: 19 arches with Sprint^{TM}	- Periodontal parameters - Levels of 5 periodontal pathogens

Risk of bias of included studies (Table 7)

The generation of the random number sequence was considered adequate in eleven trials using computer-generated random allocation (Scott *et al*., 2008a; Scott *et al*., 2008b; Fleming *et al*., 2009a; Fleming *et al*., 2009b; Fleming *et al*., 2009c; Pringle *et al*., 2009; Fleming *et al*., 2010; DiBiase *et al*., 2011; Pandis *et al*., 2011; Johansson and Lundstrom, 2012; Wong *et al*., 2012). In many of the studies allocation was performed using a quasi-random method, with consecutive subjects being alternated between appliances. However, ten trials with appropriate random allocation procedures also had acceptable allocation concealment (Scott *et al*., 2008a; Scott *et al*., 2008b; Fleming *et al*., 2009a; Fleming *et al*., 2009b; Fleming *et al*., 2009c; Pringle *et al*., 2009; Fleming *et al*., 2010; DiBiase *et al*., 2011; Pandis *et al*., 2011; Wong *et al*., 2012). Group allocation was not concealed in any of the split-mouth studies (Miles *et al*., 2006; Pandis *et al*., 2006b; Pellegrini *et al*., 2009; Buck *et al*., 2011).

In view of the visibility of fixed orthodontic appliances, blinding of either participants or personnel was not possible. It is unclear whether bias is likely to be introduced as a consequence as the outcomes were objective in most instances. However, blinding of assessors was possible and was undertaken in the great majority of studies. In studies involving assessment of pain experience (Brock, 2008; Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009; Tecco *et al*., 2009a), outcome assessment was also likely to be blinded in view of the use of coded data.

There were no dropouts in seven studies (Pandis *et al*., 2006a; Pandis *et al*., 2006b; Pandis *et al*., 2007a; Pandis *et al*., 2008a; Pandis *et al*., 2008b; Pandis *et al*., 2010a; Pandis *et al*., 2011); in studies with dropout those lost to follow-up were reported on. However, statistical analysis was invariably per-protocol with dropouts excluded from analysis. Overall, eleven studies were deemed to be at low or unclear risk of bias (Scott *et al*., 2008a; Scott *et al*., 2008b; Fleming *et al*., 2009a; Fleming *et al*., 2009b; Fleming *et al*., 2009c; Pringle *et al*., 2009; Fleming *et al*., 2010; DiBiase *et al*., 2011; Pandis *et al*., 2011; Johansson and Lundstrom, 2012; Wong *et al*., 2012). As the remaining studies were judged to be at high risk of bias with respect to random allocation procedures and allocation concealment, these studies were not considered appropriate for further analysis.

Table 7. Risk of bias of the 30 studies included in the qualitative synthesis.

Paper	Random sequence generation	Allocation concealment	Blinding participant and personnel	Blinding assessor	Free from incomplete outcome data	Free from selective reporting	Free from other bias
Miles (2005)	High	High	Unclear	High	Low	Low	Low
Miles *et al*. (2006)	High	High	Unclear	High	Low	Low	Low
Pandis *et al*. (2006a)	High	High	Unclear	High	Low	Low	Low
Pandis *et al*. (2006b)	High	High	Unclear	High	Low	Low	Low
Miles (2007)	High	High	Unclear	High	Low	Low	Low
Pandis *et al*. (2007)	High	High	Unclear	High	Low	Low	Low
Brock (2008)	High	High	Unclear	Low	Low	Low	Low
Pandis *et al*. (2008a)	High	High	Unclear	Low	Low	Low	Low
Pandis *et al*. (2008b)	High	High	Unclear	High	Low	Low	Low
Scott *et al*. (2008a)	Low	Low	Unclear	Low	Low	Low	Low
Scott *et al*. (2008b)	Low	Low	Unclear	Low	Low	Low	Low
Fleming *et al*. (2009a)	Low	Low	Unclear	Low	Low	Low	Low
Fleming *et al*. (2009b)	Low	Low	Unclear	Low	Low	Low	Low
Fleming *et al*. (2009c)	Low	Low	Unclear	Low	Low	Low	Low
Pellegrini *et al*. (2009)	High	High	Unclear	Low	Low	Low	Low
Pringle *et al* (2009)	Low	Low	Unclear	Low	Low	Low	Low
Tecco *et al*., (2009a)	High	High	Unclear	Low	Low	Low	Low
Tecco *et al*., (2009b)	High	High	Unclear	Low	Low	Low	Low
Fleming *et al*. (2010)	Low	Low	Unclear	Low	Low	Low	Low
Ong *et al*. (2010)	High	High	Unclear	Low	Low	Low	Low
Pandis *et al*. (2010a)	High	High	Unclear	High	Low	Low	Low
Pandis *et al*. (2010b)	High	High	Unclear	Low	Low	Low	Low
Buck *et al*. (2011)	High	High	Unclear	Low	Low	Low	Low
DiBiase *et al*. (2011)	Low	Low	Unclear	Low	Low	Low	Low
Pandis *et al*. (2011)	Low	Low	Unclear	Low	Low	Low	Low
Gaspar-Ribeiro *et al*. (2012)	Unclear	High	Unclear	High	Low	Low	Low
Johansson and Lundstrom (2012)	Low	Unclear	Unclear	Low	Low	Low	Low
Wahab *et al*. (2012)	Unclear	High	Unclear	Low	Low	Low	Low
Wong *et al*. (2012)	Low	Low	Unclear	Low	Low	Low	Low
Pejda *et al*. (2013)	Unclear	High	Unclear	Low	Low	Low	Low

Torque expression and arch dimensional change

In the initial search, meta-analysis of this outcome was not possible. However, further research has emerged in the interim (Pandis *et al.*, 2010a) permitting more detailed comparison in the updated review.

In relation to the mandibular arch, Pandis *et al.* (2007), Fleming *et al*. (2009a) and Pandis *et al.* (2010a) reported identical incisor proclination and inter-canine expansion with both appliance systems during arch alignment. Statistically greater inter-molar expansion with self-ligating appliances has been shown in the latter studies (Fleming *et al.,* 2009a*;* Pandis *et al.,* 2010a). These findings were not observed by Scott *et al.* (2008a*)*, although this study involved assessment following mandibular premolar extraction precluding direct comparison. Similarly, Pandis *et al.* (2011) did not demonstrate a statistical difference in the degree of either inter-canine or inter-molar expansion between the Damon MX™ appliance and a conventional system. The trials by Fleming *et al*. (2009a) and Pandis *et al.* (2011) were considered to be appropriate for meta-analysis as they had acceptable levels of bias and examined non-extraction lower arch treatment. No statistical difference was found in the degree of mandibular inter-canine or mandibular inter-molar expansion with either appliance type (Figures 4 and 5).

	SLBs			CBs				Mean Difference
Study or Subgroup	Mean [mm]	SD [mm]	Total	Mean [mm]	SD [mm]	Total	Weight	IV, Random, 95% CI [mm]
Fleming et al. (2009a)	26.52	1.3	31	26.69	1.51	29	54.1%	−0.17 [−0.89, 0.55]
Pandis et al. (2011)	27.1	1.4	25	27	1.4	25	45.9%	0.10 [−0.68, 0.88]
Total (95% CI)			**56**			**54**	**100.0%**	**−0.05 [−0.57, 0.48]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.25$, df = 1 (P = 0.62); $I^2 = 0\%$								
Test for overall effect: Z = 0.17 (P = 0.86)								

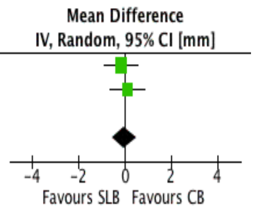


Figure 4. Meta-analysis and forest plot of mandibular inter-canine width changes with self-ligating brackets (SLBs) and conventional brackets (CBs).

	SLBs			CBs				Mean Difference
Study or Subgroup	Mean [mm]	SD [mm]	Total	Mean [mm]	SD [mm]	Total	Weight	IV, Random, 95% CI [mm]
Fleming et al. (2009a)	45.1	2.14	31	45.79	2.63	29	49.2%	−0.69 [−1.91, 0.53]
Pandis et al. (2011)	46.2	1.9	25	46.4	2.4	25	50.8%	−0.20 [−1.40, 1.00]
Total (95% CI)			**56**			**54**	**100.0%**	**−0.44 [−1.30, 0.41]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.32$, df = 1 (P = 0.57); $I^2 = 0\%$								
Test for overall effect: Z = 1.01 (P = 0.31)								

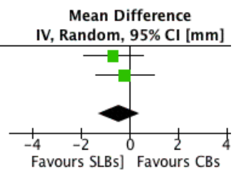


Figure 5. Meta-analysis and forest plot of mandibular inter-molar width changes with self-ligating brackets (SLBs) and conventional brackets (CBs).

Efficiency of initial orthodontic alignment

The efficiency of initial orthodontic alignment was considered in nine studies (Miles, 2005; Miles *et al*., 2006; Pandis *et al*., 2007; Scott *et al*., 2008a; Fleming *et al*., 2009c; Ong *et al*., 2010; Pandis *et al*., 2011; Gaspar-Ribeiro *et al*., 2012; Wahab *et al*., 2012). Two studies adopted three-dimensional measuring techniques making comparison with other studies impractical (Fleming *et al*., 2009c; Gaspar-Ribeiro *et al*., 2012); one of these studies was also adjudged to be at high risk of bias (Gaspar-Ribeiro *et al*., 2012). The remaining studies used two-dimensional measurement; one of these trials incorporated a split mouth design allowing consideration of just four mandibular contact points (Miles *et al*., 2006).

Alignment efficiency was assessed in the maxillary arch in one study (Ong *et al*., 2010); the remaining studies centred on the mandibular arch. Assessment was confined to the anterior teeth in most studies, while two considered irregularity from first molar to first molar (Fleming *et al*., 2009c; Gaspar-Ribeiro *et al*., 2012).

Among the parallel designs, Scott *et al*., (2008a) and Miles (2005) followed similar treatment protocols with alignment efficiency assessed using Little's irregularity index in the mandibular arch at similar intervals. Scott *et al*., (2008a) assessed changes in the irregularity index 8 weeks after appliance placement; Miles (2005) calculated residual irregularity 10 weeks and 20 weeks after placement of the appliances. However, Miles (2005) failed to include standard deviations; this study was also judged to be at high risk of bias precluding meta-analysis. Instead of measuring the amount of irregularity relieved in a given timeframe, Pandis *et al.* (2007) and Pandis *et al.* (2011) calculated the time taken for the alignment of the lower anteriors to occur, although the end points chosen differed between the studies.

In the only split-mouth study, Miles *et al.* (2006) assessed malalignment remaining after both 10 and 20 weeks of treatment. Standard deviations were not included in this report. In addition, it was unclear how discrepancies between the mandibular central incisors were handled.

Rate of orthodontic space closure

Only one study considered the rate of orthodontic space closure at intervals of 5 weeks until complete space closure was achieved (Miles, 2007). This study had an inadequate sample size with four of 18 subjects (22%) failing to complete the study. Posted archwires were used on both sides; therefore, tooth movement on one side may not have been independent of the other. The study did not involve random assignment of subjects and was therefore considered to be at high risk of bias. These shortcomings were addressed in a more recent parallel design randomised trial (Wong *et al*., 2012). However, no statistical difference in the rate of space closure could be found between three groups treated with either Damon MX^{TM} or conventional ligation with either conventional or low friction (SuperSlick^{TM}) elastomeric ligatures.

Overall treatment duration

In the initial review (Appendix 1), it was not possible to assess this outcome. However in the updated review three studies at unclear risk of bias examining this important outcome were identified (Fleming *et al*., 2010; DiBiase *et al*., 2011; Johansson and Lundstrom, 2012). Two of these studies were extensions of earlier interim reports (Fleming *et al*., 2010; DiBiase *et al*., 2011). These three studies were considered comparable although mandibular first premolars were extracted in one study (DiBiase *et al*., 2011), while the lower arch was treated on a non-extraction basis in another trial (Fleming *et al*., 2010). This difference may have contributed to the slightly shorter treatment times referred to in the latter study. Overall there was little difference in the treatment duration, although treatment took slightly longer with self-ligating bracket systems in each study (1.5 to 3.1 months). A statistically significant difference in treatment duration was found in the meta-analysis (Figure 6) with a mean increase in length of 2.19 months with self-ligating systems (WMD: 2.19, 95% CI: 0.4, 3.98).

	SLBs			CBs				Mean Difference
Study or Subgroup	Mean [Months]	SD [Months]	Total	Mean [Months]	SD [Months]	Total	Weight	IV, Random, 95% CI [Months]
DiBiase et al. (2011)	24.5	6.72	27	23	4.86	21	29.9%	1.50 [-1.78, 4.78]
Fleming et al. (2010)	21.4	8.44	24	18.3	4.66	28	22.3%	3.10 [-0.69, 6.89]
Johannson (2012)	20.4	5.97	44	18.2	6.56	46	47.8%	2.20 [-0.39, 4.79]
Total (95% CI)			**95**			**95**	**100.0%**	**2.19 [0.40, 3.98]**

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.39, df = 2 (P = 0.82); I^2 = 0%
Test for overall effect: Z = 2.40 (P = 0.02)

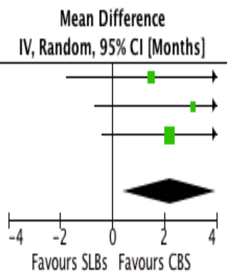


Figure 6. Meta-analysis and forest plot of overall treatment duration with self-ligating brackets (SLBs) and conventional brackets (CBs).

Subjective pain experience

Subjective pain experience was investigated following initial placement of the appliances in six studies (Miles *et al.,* 2006; Brock, 2008; Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009; Tecco *et al*., 2009a); three of these were randomised trials (Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009). Of the six studies, one split-mouth study considered pain reports after both the first and second visits, with patients indicating which system was associated with greatest discomfort (Miles *et al.,* 2006). Data in four of the trials are presented as continuous pain scores on a 100mm VAS (Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009; Tecco *et al*., 2009a). One trial reported pain scores at fifteen time intervals (Pringle *et al*., 2009); two trials used four time points: 4 hours, 24 hours, 3 days and 7 days after appliance placement. The findings from these studies conflicted slightly with one study reporting a tendency to less pain experience with Damon MX^{TM} self-ligating brackets, although this finding did not reach statistical significance (Pringle *et al*., 2009). Reported pain peaked within 24 hours (Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009) before subsiding to near baseline levels 7 days after appliance placement. Three studies were regarded as being at low risk of bias and reported similar outcomes permitting statistical comparison (Scott *et al*., 2008b; Fleming *et al*., 2009b; Pringle *et al*., 2009); pain scores at four analogous time intervals were extracted from each study to facilitate this (Pringle *et al*., 2009). Pain intensity over the first 7 days was reported in three studies, which involved 160 patients with 83 having treatment with SLBs and 77 with conventional appliances. Participants undergoing treatment with SLBs reported a mean difference in pain intensity of 0.99 to 5.66 points lower than was found with CBs with the greatest difference reported 3 days after appliance placement (Figures 7 to 10). However, differences were not of statistical significance.

	SLB			CB				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Fleming et al., 2009	46.81	24.41	26	46.43	24.07	22	31.3%	0.38 [-13.37, 14.13]
Pringle et al., 2009	33.71	25.2	24	43.71	30.11	28	26.2%	-10.00 [-25.03, 5.03]
Scott et al., 2007	63.67	23.18	33	60.11	23.3	27	42.4%	3.56 [-8.26, 15.38]
Total (95% CI)			**83**			**77**	**100.0%**	**-0.99 [-8.69, 6.71]**

Heterogeneity: Chi² = 1.99, df = 2 (P = 0.37); I² = 0%
Test for overall effect: Z = 0.25 (P = 0.80)

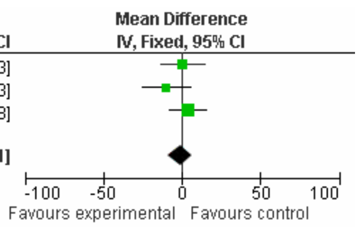


Figure 7. Meta-analysis and forest plot of pain scores (VAS) 4 hours after appliance placement in experimental (SLBs) and control (CBs) groups.

Study or Subgroup	SLB Mean	SLB SD	SLB Total	CB Mean	CB SD	CB Total	Weight	Mean Difference IV, Fixed, 95% CI
Fleming et al., 2009	61.46	25.35	26	67.7	17.83	22	34.5%	-6.24 [-18.51, 6.03]
Pringle et al., 2009	24.58	22.8	24	35.21	28.4	28	26.7%	-10.63 [-24.55, 3.29]
Scott et al., 2007	58.3	20.74	33	57.44	24.24	27	38.8%	0.86 [-10.70, 12.42]
Total (95% CI)			**83**			**77**	**100.0%**	**-4.66 [-11.86, 2.54]**

Heterogeneity: Chi² = 1.65, df = 2 (P = 0.44); I² = 0%
Test for overall effect: Z = 1.27 (P = 0.20)

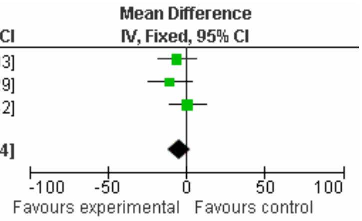


Figure 8. Meta-analysis and forest plot of pain scores (VAS) 24 hours after appliance placement in experimental (SLBs) and control (CBs) groups.

Study or Subgroup	SLB Mean	SLB SD	SLB Total	CB Mean	CB SD	CB Total	Weight	Mean Difference IV, Fixed, 95% CI
Fleming et al., 2009	42.58	23.87	26	46.45	24.15	22	22.4%	-3.87 [-17.51, 9.77]
Pringle et al., 2009	5.67	7	24	17.29	23	28	51.8%	-11.62 [-20.59, -2.65]
Scott et al., 2007	42.94	23.08	33	38.19	26.43	27	25.8%	4.75 [-7.95, 17.45]
Total (95% CI)			**83**			**77**	**100.0%**	**-5.66 [-12.11, 0.79]**

Heterogeneity: Chi² = 4.34, df = 2 (P = 0.11); I² = 54%
Test for overall effect: Z = 1.72 (P = 0.09)

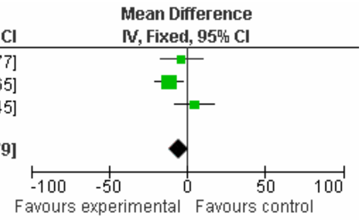


Figure 9. Meta-analysis and forest plot of pain scores (VAS) 72 hours after appliance placement in experimental (SLBs) and control (CBs) groups.

Study or Subgroup	SLB Mean	SLB SD	SLB Total	CB Mean	CB SD	CB Total	Weight	Mean Difference IV, Fixed, 95% CI
Fleming et al., 2009	17.08	16.47	26	18.52	18.31	22	15.6%	-1.44 [-11.37, 8.49]
Pringle et al., 2009	0.71	1.84	24	5.93	12.88	28	65.9%	-5.22 [-10.05, -0.39]
Scott et al., 2007	15.12	14.32	33	15.11	20.32	27	18.6%	0.01 [-9.08, 9.10]
Total (95% CI)			**83**			**77**	**100.0%**	**-3.66 [-7.58, 0.26]**

Heterogeneity: Chi² = 1.22, df = 2 (P = 0.54); I² = 0%
Test for overall effect: Z = 1.83 (P = 0.07)

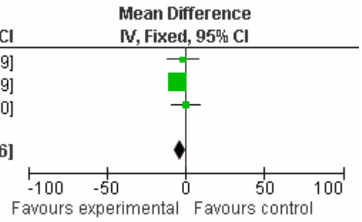


Figure 10. Meta-analysis and forest plot of pain scores (VAS) 7 days after appliance placement in experimental (SLBs) and control (CBs) groups.

Bond failure risk

Two studies have considered failure of bonded attachments over 20 weeks (Miles *et al*., 2006) and 12 months (Pandis *et al*., 2006a). The date used for assessing failure or time taken for failure to occur was not reported; only first-time failures for each tooth were recorded. No significant differences were noted in the more extensive study (Pandis *et al*., 2006a).

Plaque retention and periodontal health

Three controlled clinical trials have involved comparison of the impact of self-ligating brackets and elastomeric ligation on plaque retention (Pellegrini *et al*., 2009; Pandis *et al*., 2010b; Buck *et al*., 2011). A split-mouth design was used in one study assaying plaque specimens harnessed 1 and 5 weeks after bonding (Pellegrini *et al*., 2009); this study was extended to 12 months to facilitate a more detailed analysis (Buck *et al*., 2011). More permanent effects of bracket system on periodontal health and accumulation of debris have also been assessed (Pandis *et al*., 2008a).

Pellegrini *et al.* (2009) investigated the influence of method of archwire ligation on plaque retention using ATP-driven bioluminescence to assess bacterial load. Mean streptococcal and total bacterial levels harvested from tooth surfaces were lower with the self-ligating bracket ($p<0.05$). A further prospective trial, however, failed to show an association between bracket type and bacterial load (Pandis *et al*., 2010b). This finding may reflect the different measurement technique deployed involving estimation of salivary levels of Streptococcus mutans.

Furthermore, Pandis *et al.* (2010b) failed to demonstrate a link between bracket type and periodontal health following removal of orthodontic appliances. It appears that, while bracket type may influence bacterial load with appliances *in situ*, this effect may not be sustained following treatment. None of these studies were of low risk of bias precluding statistical analysis.

Statistical heterogeneity, publication bias and quality of evidence (GRADE).

The degree of heterogeneity between studies in the analyses of transverse dimensional change and treatment duration was found to be low (I^2= 0%). Statistical analysis of publication bias was not indicated, as less than ten studies were included in the quantitative synthesis. The GRADE assessment of the quality of the evidence was considered to be high (Table 8). This suggests that further research is unlikely to have a significant impact on confidence in the effect estimate.

Table 8. GRADE assessment of quality of reports comparing mandibular inter-canine and inter-molar width changes, treatment duration, and pain scores (24 hours) with self-ligating and conventional systems.

Population: Patients with malocclusion **Settings:** Hospital/Community Orthodontic Departments or private practice **Intervention:** Self-ligating brackets (SLBs) **Comparison:** Conventional brackets (CBs)				
Outcomes			**Number of participants (studies)**	**Quality of the evidence (GRADE)**
	CBs	**SLBs**		
Mandibular inter-canine width	The range of the mean width in the control groups was **26.69 to 27 mm**	The mean width in the intervention groups was **0.05 mm higher** (0.57 lower to 0.48 higher)	110 (2 studies)	⊕⊕⊕⊕ **high**[1,2,3]
Mandibular inter-molar width	The range of the mean width in the control groups was **45.79 to 46.4 mm**	The mean width in the intervention groups was **0.44 mm higher** (.41 lower to 1.30 higher)	110 (2 studies)	⊕⊕⊕⊕ **high**[1,2,3]
Treatment duration	The range of the mean duration in the control group was **18.2 to 23 months**	The mean treatment duration in the intervention groups was **2.19 months higher** (3.98 to 0.4 higher)	192 (3 studies)	⊕⊕⊕⊕ **high**[1,2]
Subjective pain experience (24 hours)	The range of the mean pain scores in the control group was **35.2 to 67.7**	The mean pain score in the intervention groups was **4.66 lower** (11.86 lower to 2.54 higher)	160 (3 studies)	⊕⊕⊕⊕ **high**[1,2,3]

Footnotes

[1] Statistical heterogeneity was minimal (I^2= 0%). It was decided not to rate the evidence down.
[2] No indirectness as all studies included head to head comparisons with similar inclusion/exclusion criteria. It was decided not to rate the evidence down.
[3] Confidence intervals (CIs) overlap and although estimates were in both directions the difference is small. It was decided not to rate the evidence down.

4.4 Discussion

The majority of the studies included were considered to be at high risk of bias; the chief problem with most studies related to the randomisation procedures. While some studies were described by the authors as randomised controlled trials, a number of studies were mislabeled as randomised trials as the method of randomisation and allocation concealment was either inadequate or incompletely reported. In addition, many studies used determinate methods of allocation, including alternate allocation, which precluded concealment of the participant to group allocation.

Further methodological and reporting shortcomings included failure to present *a priori* sample size calculations and CONSORT flow diagrams. Sample size calculations were reported in only 10 studies, one of these was retrospective (Johansson and Lundstrom, 2012), potentially compromising the precision of the results and increasing the risk of false negative outcomes. The use of participant flow diagrams delineating the recruitment and outcome of participants in randomised trials is encouraged (Schulz *et al*., 2010) and is generally implemented in medical research studies (Mills *et al*., 2005). However, of the 30 studies included in this review, just eight included a CONSORT flow diagram (Pringle *et al*., 2009; Scott *et al*., 2008a; Scott *et al*., 2008b; Pandis *et al*., 2010a; DiBiase *et al*., 2011; Pandis *et al*., 2011; Johansson and Lundstrom, 2012; Wong *et al*., 2013).

Per-protocol analysis was used in all studies with dropouts being excluded from statistical analyses. Intention-to-treat analysis may be a more appropriate technique ensuring consideration of all subjects initially randomised, maintaining the benefits of randomisation throughout the trial, particularly in the case of a large number of losses or unbalanced dropout rates. However, in seven studies no dropouts were reported; in the remaining studies dropouts were clearly outlined. Consequently, the risk of bias derived from incomplete outcome data was generally low.

It is important that further prospective research in this area is reported in accordance with the CONSORT guidelines (Schulz *et al*., 2010); this will improve the quality of reporting, and indirectly is likely to enhance the methodological quality of research studies. Accurate and transparent reporting will also lead to simpler and more accurate assessment of the evidence facilitating synthesis where appropriate.

Arch dimensional changes arising with self-ligating brackets and conventional systems appear to be similar with identical levels of incisor proclination and inter-canine expansion developing with both systems (Pandis *et al*., 2007; Pandis *et al*., 2006b; Fleming *et al*., 2009b; Pandis *et al*., 2010a). This outcome is at odds with claims that low friction systems may respond differently under soft tissue pressures. Nevertheless, two studies have suggested greater mandibular inter-molar expansion develops during alignment with SLBs (Fleming *et al*., 2009b; Pandis *et al*., 2010a). However, meta-analysis of comparable studies of unclear risk of bias failed to demonstrate a statistical difference is mandibular inter-canine and inter-molar width changes with the two systems. Comparison of transverse changes in the maxillary arch with self-ligation and conventional systems has not yet been considered in a randomised controlled trial.

In the earlier systematic review (Appendix 1) prospective research relating to overall treatment duration and number of visits was not available. Consequently, it was only possible to consider surrogate measures of treatment efficiency including the efficiency of orthodontic alignment and the rate of space closure in the initial systematic review (Appendix 1). These studies demonstrated little difference between fixed appliance types with remarkable consistency, contradicting retrospective research findings (Harradine, 2001; Eberting *et al*., 2001) and being incompatible with manufacturers' claims of superior clinical performance with SLBs. However, statistical comparison of these studies was not performed in view of differences in measuring alignment, methodological inadequacies related to some of the research and incomplete reporting of results. In the updated review, however, prospective reports concerning treatment in its entirety were available. All three studies (Fleming *et al*., 2010; DiBiase *et al*., 2011; Johansson and Lundstrom, 2012) were RCTs and were conducted in hospital or public healthcare settings with the reported treatment time marginally, but consistently, longer with SLBs in keeping with earlier prospective studies. In addition, all three studies referred to similar occlusal outcomes with both bracket systems, based on either the PAR index (Fleming *et al*., 2010; DiBiase *et al*., 2011) or ICON score (Johansson and Lundstrom, 2012). On the basis of this research it is doubtful whether a fixed appliance system may have a significant bearing on the duration of orthodontic treatment or on the number of visits required. Moreover, the skill, experience and objectives of the treating clinician in addition to the dictates of the presenting malocclusion are likely to override any potential difference in treatment efficiency due to bracket type.

Meta-analysis of the influence of bracket type on pain experience confirmed that self-ligating brackets do not have a clinically significant bearing on subjective pain experience. The three studies included in the meta-analysis had discordant findings with one favouring SLBs (Pringle *et al*., 2009); the other two studies demonstrated little difference between the appliance systems. We can only speculate as to why this discrepancy arose; all studies were of high methodological quality and were carried out in similar settings, with analogous age and gender distributions alignment (Pringle *et al*., 2009; Fleming *et al*., 2009b; Scott *et al*., 2008b). The failure to highlight a significant bracket-related effect is compatible with previous research, which has failed to demonstrate a link between archwire material (Jones and Chan, 1992) or dimension

(Erdinc and Dincer, 2004), and pain experience. Clearly, pain is influenced by a variety of factors with individual susceptibility being critical. Consequently, to definitively address this question a well-designed, prospective study of a large sample is required.

The finding of lower bacterial and Streptococcal loads surrounding SLBs than conventional brackets during the initial stages of orthodontic treatment is of interest (Pellegrini *et al*., 2009). Longer-term follow-up has highlighted the capacity of periodontal tissues to recover from this initial insult following appliance removal (Pandis *et al*., 2008a). Nevertheless, it is unclear whether increased plaque accumulation may have other detrimental effects, particularly demineralisation. Further research is required to investigate this relationship further.

While evidence in relation to the clinical application of SLBs is beginning to accumulate, there are questions that remain unanswered. Further well-designed randomised trials are required in those areas where uncertainty persists. In particular, there has been little consideration of patient experiences during appliance therapy. Furthermore, a body of practitioners continue to advocate use of self-ligating brackets to justify a non-extraction based approach to orthodontic treatment. Consequently, further research on the effects of these systems on transverse and sagittal changes would be welcome.

4.5 Conclusions

- There is insufficient evidence to suggest that self-ligating fixed orthodontic appliances deliver different outcomes to conventional appliance systems.
- There is also no evidence to suggest a difference in treatment effects on mandibular arch inter-canine or inter-molar width changes with SLBs. Self-ligating brackets do not confer particular advantage with regard to subjective pain experience.
- There is no evidence to suggest that orthodontic treatment is more efficient with self-ligating brackets. Meta-analysis of 3 randomised controlled trials suggests that overall treatment time with SLBs may be marginally longer than with conventional systems.

CHAPTER 5. ORTHODONTIC MEASUREMENTS ON DIGITAL STUDY MODELS COMPARED WITH PLASTER MODELS: A SYSTEMATIC REVIEW.

5.1 Objective

This review aimed to evaluate the validity (Roberts and Richmond, 1997) of the use of digital models to assess a range of linear measurements of relevance to orthodontic treatment including arch width, tooth size, arch length, irregularity index, and crowding, versus measurements generated on hand-held plaster models with digital callipers in patients with and without malocclusion.

5.2 Materials and methods

To be included in the review, trials had to meet the following inclusion criteria:

• Study design: Primary diagnostic study reporting consecutive, randomly selected or non-randomly selected subjects.
• Population: Treated and untreated orthodontic patients with or without malocclusion. Restrictions were not applied due to age, gender or setting; however, alginate impressions were to be poured within 24 hours. Subjects with cleft lip and palate and other craniofacial anomalies were to be excluded.
• Index test: Measurements on digital models (any) with compatible software
• Reference standard/comparator: Measurements on unmarked plaster models (with dial or digital callipers)
• Outcome measures of interest included the validity of recordings of tooth size; transverse dimensions, irregularity index; arch width; crowding; Bolton ratio; occlusal indices; and inter-arch occlusal features. Time taken to measure hand held plaster and digital models was also assessed.

Search Strategy for Identification of Studies

An initial search was undertaken in January 2010 for an initial review (Appendix 1); this was updated in January 2013 using the same electronic databases as initially accessed: MEDLINE via OVID (1950 to January 2013), LILACS and BBO (1982 to January 2013). Language restrictions were not applied. Unpublished literature was to be identified through searches of ClinicalTrials.gov (www.clinicaltrials.gov), the National Research Register (www.controlled-trials.com) and Pro-Quest Dissertation Abstracts and Thesis database (www.lib.umi.com./dissertations). Search strategies are described in Table 9 according to the sources searched. Authors were to be contacted to identify unpublished or ongoing research and to clarify findings as required. Reference lists of the included studies were also screened for potentially relevant research.

Table 9. Database search and study selection.

Database	**Keywords**	**Results**	**Full articles retrieved**	**Articles selected**
MEDLINE via OVID (1950 to January 2013)	((digital$ or virtual or electronic or computer$ or software) and (model$ or cast$)) or emodel or orthocad) and ((plaster$ or stone or gypsum) and (model$ or cast$)) and (dental or orthod$ or tooth))	235	39	21
LILACS (1982 to 2013)	((digital$ or virtual or electronic$ or comput$ or software) and (model$ or cast$)) or emodel or orthocad) and ((plaster$ or gesso$ or stone or gypsum) and (model$ or cast$)) and (dent$ or orthod$ or tooth))	79	1	1
BBO	As LILACS above	88	1	1
IBECS	As LILACS above	3	0	0
ClinicalTrials.gov	orthodontic and digital and plaster model	0	0	0
National Research Register	orthodontic and digital and plaster model	0	0	0
Pro-Quest Dissertation Abstracts and Thesis database	“orthodontic*”, “model*” and “digital*”	0	0	0

Assessment of Relevance, Methodological Quality, and Data Extraction

Assessment of research for inclusion in the review, quality assessment and extraction of data were performed independently by two investigators (PSF, AJ). Disagreements were resolved by joint discussion, and a third investigator (Valeria Marinho) was consulted where necessary.

Potentially relevant abstracts were selected and full text articles were retrieved for further screening. Researchers were not blinded to the authors or the results of the research. Data extracted on the characteristics of included studies broadly covered the following aspects: Setting; participants; study design; reference standard(s); index /comparator test(s), number of examiners; and number of times the test was performed. Methodological quality was assessed by critically examining the methodology of the investigations. The QUADAS (Quality Assessment of Diagnostic Accuracy Studies) checklist was followed, although not all items were strictly applicable, as this review was not directly addressing diagnostic test accuracy.

Data Synthesis

Heterogeneity between studies was gauged by referring to: assessment measurement protocol/measurement technique; number of operators; and the outcome measure reporting the comparisons between the index and reference tests. Results were tabulated according to outcomes showing the estimates of the various measurements. The differences between the means of measurements on plaster and digital models were extracted. The narrative focus was on reporting the pattern of results by outcomes across all the included studies. Inferential statistical methods were not used for the estimation of summary measures, testing of differences between models/tests, and investigations of heterogeneity. No tests or investigations were undertaken to detect reporting biases.

5.3 Results

Description of included studies

In the updated search fifty-five abstracts were considered potentially relevant. Following screening, thirty-nine full-text articles were retrieved. Of these, eighteen failed to meet the inclusion criteria. Therefore, 21 articles were included in the review

(Figure 11); one of these was identified on 3 database searches (Watanabe-Kanno *et al*., 2009). Four additional articles were therefore identified in the updated search in January 2013 (Mangiacapra *et al*., 2009; Naidu *et al*., 2009; Watanabe-Kanno *et al*., 2010; Abizadeh *et al*., 2012). Reasons for exclusion at the final selection stage are outlined in Table 10.

Table 10. Excluded reports with reasons for omission.

Article	Reason excluded
Sander and Tochtermann (1991)	Description of a hologram technique; not compared to digital caliper method.
Miras and Sander (1993)	Comparison of hologram technique to sliding caliper.
Ikeuchi (1996)	Non-dental measurement of spherical objects.
Schirmer and Wiltshire (1997)	Comparison of measurement on photocopies of models and vernier caliper.
Ho and Freer (1999)	Report described development of computer program to calculate tooth size and Bolton discrepancy
Commer *et al.* (2000)	Co-ordinate measurement table used as reference
Zilberman *et al.* (2003)	Used artificial occlual setup.
Asquith *et al.* (2007)	Points were marked on plaster models
Gracco *et al.* (2007)	Used artificial occlusal setup.
Alcan *et al.* (2009)	Used artificial occlusal setup. Time lag in excess of 24 hours before impressions poured.
Dalstra and Melsen (2009)	Time lag in excess of 24 hours before impressions poured.
Sjogren *et al.* (2010)	Points were marked on plaster models
Torassian *et al.* (2010)	Used artificial occlusal setup.
Chawla *et al.* (2012)	Cleft lip and palate
Sousa *et al.* (2012)	Incompatible scanning and measurement programs used
Wiranto *et al.* (2012)	Time lag of up to 48 hours before impressions poured. Digital models derived from CBCT.
Asquith and McIntyre (2012)	Cleft lip and palate
Chawla *et al.* (2013)	Cleft lip and palate

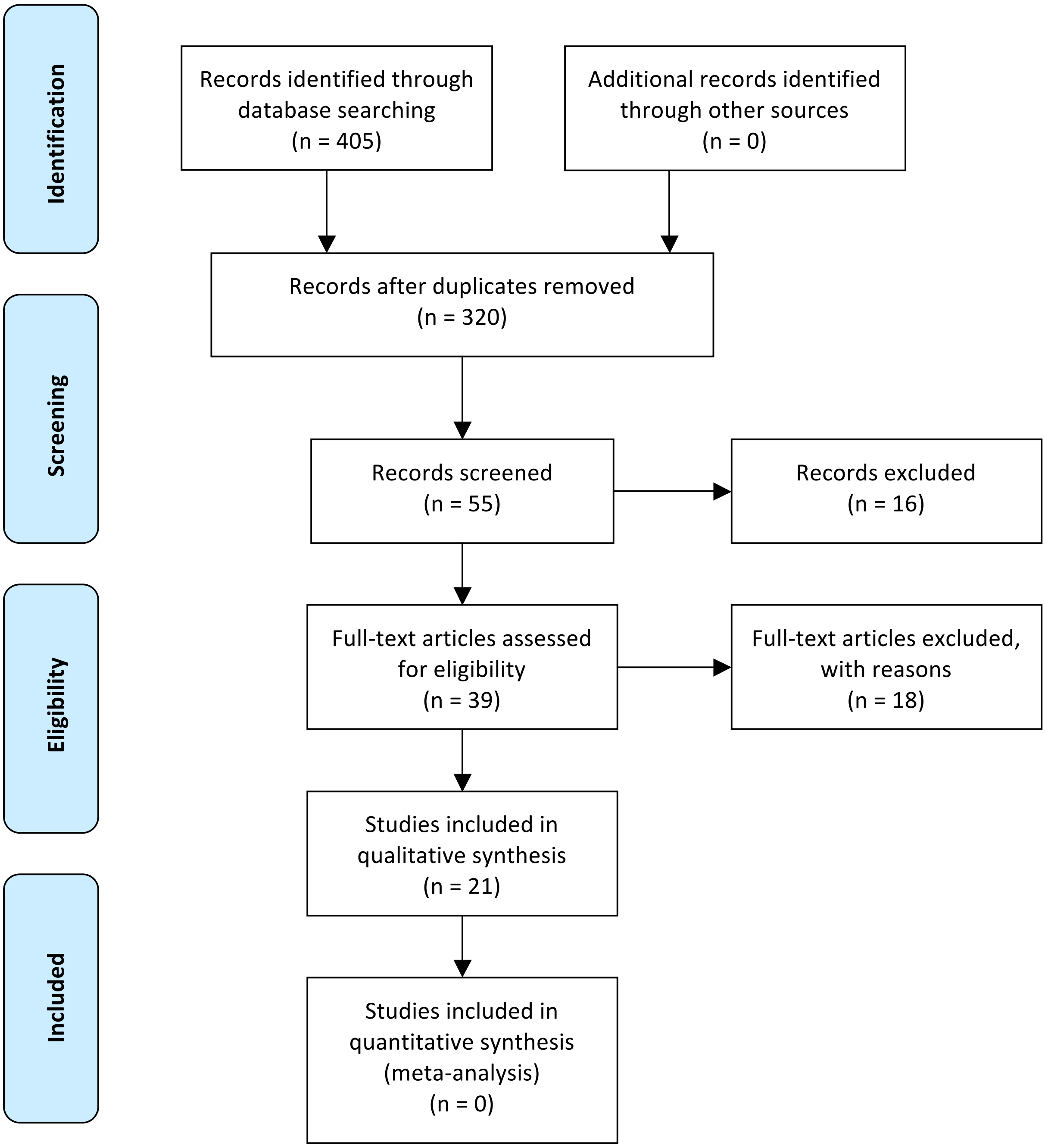


Figure 11. Flow diagram of article retrieval.

The characteristics of the individual studies are given in Table 11. All investigations were based in dental University settings, typically in the permanent dentition. Subjects in the majority of studies had malocclusion and had no history of orthodontic treatment. Gender and ethnicity were unspecified in all studies. Subjects were aged 12 to 18 years in two studies (Watanabe-Kanno *et al*., 2009; Watanabe-Kanno *et al*., 2010) but age was unclear in the remainder. Clear information on study design was lacking in the majority of reports.

Nine digital model systems were assessed in these trials: OrthoCad™; emodels™; C3D-builder™; ConoProbe™; Easy3D Scan™; Ortho3D™; Digimodels™; 3Shape™; and Cecile 3™. Agreement between recordings on OrthoCad and plaster models was assessed in nine studies (Tomassetti *et al*., 2001; Santoro *et al*., 2003; Quimby *et al*., 2004; Mayers *et al*., 2005; Costalos *et al*., 2005; Okunami *et al*., 2007; Hildenbrand *et al*., 2008; Goonewardene *et al*., 2008; Leifert *et al*., 2009), between emodels™ and plaster models in three investigations (Stevens *et al*., 2006; Mullen *et al*., 2007; Horton *et al*., 2010), on both Digimodels™ (Veenema *et al*., 2009; Naidu et al., 2009) and Cecile3™ in two studies (Watanabe-Kanno *et al*., 2009; Watanabe-Kanno *et al*., 2010) and using the other software systems in a single study each. Similar types of plaster models (index/comparator test) were used in each study. All digital recordings were compared to those derived from direct measurement on plaster models using digital calipers. Either one or two (Santoro *et al*., 2003; Quimby *et al*., 2004; Mayers *et al*., 2005; Stevens *et al*., 2006; Mangiacapra *et al*., 2009) sets of impressions were taken to produce digital and plaster models.

Significant variation was observed in the number of examiners carrying out the measurements and the number of time the readings were repeated. Ten examiners performed measurements in one trial (Quimby *et al*., 2004) and twenty in a further study (Mangiacapra *et al*. (2009). Measurements were carried out three times by one or more researchers in five studies (Tomassetti *et al*., 2001, Stevens *et al*., 2006; Redlich *et al*., 2008; Naidu *et al.,* 2009; Horton *et al*., 2010) and eight times in one study (Bell *et al*., 2003).

Table 11. Characteristics of the 21 studies included in qualitative synthesis.

Study	**Characteristics of participants**	**Study design**	**Index test/ Reference standard**	**Examiners (readings per examiner)**	**Outcome measures**
Tomassetti *et al*. (2001)	22 subjects; USA; 11 pre- and 11 post-treatment; not more than 3mm crowding.	Prospective	OrthoCad^{TM}/ Digital calipers	1 (3)	Bolton ratio; Time taken
Santoro *et al*. (2003)	20 subjects; USA; permanent dentition; no missing teeth; stable occlusion with 3 occlusal contacts or more.	Prospective, enrolled randomly	OrthoCad^{TM}/ Digital calipers	2 (1)	Tooth size; Overjet; Overbite
Bell *et al*. (2003)	22 subjects; UK	Prospective	C3D-builder^{TM} (Uni. of Glasgow) /Digital calipers	1 (8)	Transverse and sagittal linear measurements
Quimby *et al*. (2004)	50 subjects; USA; permanent dentition	Prospective, enrolled consecutively	OrthoCad^{TM}/ Digital calipers	10 (2)	Tooth size; Arch length; Transverse dimension; Overjet; Overbite; Space available; Space required

Mayers *et al*. (2005)	48 subjects; USA; permanent dentition	Prospective, enrolled consecutively	OrthoCad^{TM}/ Digital calipers	1 (2)	PAR score
Costalos *et al*. (2005)	48 subjects; USA; permanent dentition; post-treatment; no edentulous space; no malocclusion.	Prospective	OrthoCad^{TM}/ Digital calipers	2 (1)	ABO score
Stevens *et al*. (2006)	24 subjects; Canada; complete permanent dentition (from 1st molar to 1st molar) without previous orthodontics, pre-treatment models	Prospective, randomly selected from 225 records; three selected within each of 8 categories of malocclusion	emodels^{TM}/ Digital calipers	3 (3 and 1)	PAR; Bolton ratio
Mullen *et al*. (2007)	30 subjects; USA; pre-treatment; complete permanent dentition.	Prospective	emodels^{TM}/ Digital calipers	1 (1)	Bolton ratio; Time taken
Okunami *et al*. (2007)	30 subjects; USA; permanent dentition; post-treatment; no malocclusion.	Prospective	OrthoCad^{TM}/ Digital calipers	1 (1)	ABO score

Redlich *et al*. (2008)	30 subjects; Israel; mixed and permanent dentition; 10 subjects each with mild, moderate and severe crowding.	Prospective	ConoProbe^{TM}/ Digital calipers	1 (3)	Tooth width; Arch length; Crowding
Hildebrand *et al*. (2008)	36 subjects; USA; treated cases; consenting patients; no malocclusion.	Prospective, enrolled randomly	OrthoCad^{TM}/ Digital calipers	1 (1)	ABO score
Goonewardene *et al*. (2008)	50 subjects; Australia; permanent dentition erupted including third molars.	Prospective	OrthoCad^{TM}/ Digital calipers	1 (1)	Tooth width; Arch length; Crowding Irregularity
Keating *et al*. (2008)	30 subjects; UK	Prospective, enrolled randomly	Easy3D Scan^{TM}/Digital calipers	1 (2)	Linear dimensions (x, y, z planes)
Mangiacapra *et al*., 2009	5 subjects; Italy; various malocclusion types and range of crowding.	Prospective	Ortho3D^{TM}/ Digital calipers	20 (2)	Tooth size; Transverse dimension; Overbite

Veenema *et al*. (2009)	30 subjects; Holland; pre- and post-treatment; permanent dentition; 5 Class I, 19 Class II div 1, 5 Class II div 2, 1 Class III; 5 treated with extractions.	Prospective, enrolled randomly	Digimodel^{TM}/ Digital calipers	2 (1)	ICON score
Leifert *et al*. (2009)	25 subjects; USA; Class I molar relationship, crowding.	Prospective, enrolled consecutively	OrthoCad^{TM}/ Digital calipers	2 (1)	Crowding
Watanabe-Kanno *et al*. (2009)	15 subjects; Brazil; permanent dentition; pre-treatment; 12-18 years.	Prospective	Cecile3^{TM}/ Digital calipers	2 (1)	Transverse dimensions; Tooth size; Overjet; Overbite
Naidu *et al*., 2009	25 subjects; Australia; permanent dentition with 12 erupted teeth per arch; pre-treatment.	Prospective	Digimodel^{TM}/ Digital calipers/ Photographs of models	3 (3 or 1)	Tooth size; Bolton ratio
Watanabe-Kanno *et al*. (2010)	15 subjects; Brazil; permanent dentition; pre-treatment; 12-18 years.	Prospective	Cecile3^{TM}/Digital calipers	2 (1)	Bolton ratio; Crowding

Horton *et al*. (2010)	32 subjects; USA; permanent dentition; pre-treatment.	Prospective	emodels^{TM}/ Digital calipers	1 (3)	Tooth size; Time taken
Abizadeh *et al.* (2012)	112 subjects; UK; permanent dentition with 12 erupted teeth per arch; pre-treatment; 38 Class I, 38 Class II, 36 Class III; 38 with mild crowding, 38 moderate crowding, 36 severe crowding	Prospective	3 Shape^{TM}/ Digital calipers	1 (2)	Transverse dimensions; Tooth size; Arch length; Overjet; Overbite; Centreline discrepancy; Crown height

Methodological quality of included studies

Where possible the Quality Assessment of Studies of Diagnostic Accuracy included in Systematic Reviews (QUADAS) tool (Whiting *et al*., 2003) was adhered to. Therefore, methodological quality was assessed by critically examining the investigations in relation to: inclusion of a representative spectrum of patients (population recruitment and characteristics); use of appropriate reference standards; adequate description of index tests and reference standards; independent interpretation of the tests; independent interpretation of index and reference tests; and reporting of uninterpretable or intermediate data (Table 12).

Regarding the inclusion of a representative spectrum of patients, subjects were recruited either randomly or consecutively in most studies although the recruitment process and the characteristics of those recruited was not clearly outlined in nine studies (Tomassetti *et al*., 2001; Bell *et al*., 2003; Costalos *et al*., 2005; Mullen *et al*., 2007; Okunami *et al*., 2007; Redlich *et al*., 2008; Goonewardene *et al*., 2008; Mangiacapra *et al*., 2009; Horton *et al*., 2010). A clear definition of the criteria used for entry into the studies was also omitted from these studies. Measurements were undertaken on both the index test and an appropriate reference standard in all studies with those on the plaster models performed independently of the digital models in all studies. In 15 studies the index test and reference standard were not independent both being derived from the same impression; separate impressions were taken in the remaining six studies (Santoro *et al*., 2003; Quimby *et al*., 2004; Mayers *et al*., 2005; Stevens *et al*., 2006; Naidu *et al*., 2009; Mangiacapra *et al*., 2009).

Blinded interpretation of results was precluded by obvious differences in the performance of digital and manual measurements. All investigations were performed prospectively with sample size estimation reported in just five studies (Bell *et al*., 2003; Quimby *et al*., 2004; Stevens *et al*., 2006; Goonewardene *et al*., 2008; Keating *et al*., 2008).

Table 12. Methodological quality of included studies (n=21) using items from QUADAS.

Study	Represent-ative spectrum of patients	Reference standard appropriate	Index test well-described	Reference standard independent of index test	Reference test described	Results of each test interpreted in isolation	Uninterpretable intermediate results reported
Tomassetti *et al*. (2001)	Unclear	Yes	Yes	No	Yes	Unclear	No
Santoro *et al*. (2003)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Bell *et al*. (2003)	Unclear	Yes	Yes	No	Yes	Unclear	No
Quimby *et al*. (2004)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Mayers *et al*. (2005)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Costalos *et al*. (2005)	Unclear	Yes	Yes	No	Yes	Unclear	No
Stevens *et al*. (2006)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Mullen *et al*. (2007)	Unclear	Yes	Yes	No	Yes	Unclear	No
Okunami *et al*. (2007)	Unclear	Yes	Yes	No	Yes	Unclear	No
Redlich *et al*. (2008)	Unclear	Yes	Yes	No	Yes	Unclear	No
Hildebrand *et al*. (2008)	Yes	Yes	Yes	No	Yes	Unclear	No
Goonewardene *et al*. (2008)	Unclear	Yes	Yes	No	Yes	Unclear	No
Keating *et al*. (2008)	Yes	Yes	Yes	No	Yes	Unclear	No
Veenema *et al*. (2009)	Yes	Yes	Yes	No	Yes	Unclear	No
Leifert *et al*. (2009)	Yes	Yes	Yes	No	Yes	Unclear	No
Watanabe-Kanno *et al*. (2009)	Yes	Yes	Yes	No	Yes	Unclear	No
Mangiacapra *et al*. (2009)	Unclear	Yes	Yes	Yes	Yes	Unclear	No
Naidu *et al*., 2009	Yes	Yes	Yes	Yes	Yes	Unclear	No
Watanabe-Kanno *et al*. (2010)	Yes	Yes	Yes	No	Yes	Unclear	No

Horton *et al*. (2010)	Unclear	Yes	Yes	No	Yes	Unclear	No
Abizadeh *et al.,* 2012	Yes	Yes	Yes	No	Yes	Unclear	No

Results by outcome measured

Outcomes assessed include the validity of analysis of transverse dimensions; other miscellaneous linear measurements; tooth size; Bolton ratio; arch length and crowding; irregularity index; inter-arch occlusal features; occlusal indices; and time taken to perform measurements using the two approaches. No studies investigating the validity of angular measurements on digital models were found. The results are presented in Tables 13 to 15.

Transverse dimensional measurements

The agreement between transverse dimensional readings obtained using digital and plaster models has been assessed in six studies (Bell *et al*., 2003; Quimby *et al*., 2004; Keating *et al*., 2008; Watanabe-Kanno *et al*., 2009; Mangiacapra *et al*., 2009; Abizadeh *et al*., 2012). Dimensions considered include mandibular and maxillary inter-canine, inter-premolar and inter-molar dimensions. Mean discrepancies between the approaches ranged from 0.04 to 0.4mm (Quimby *et al*., 2004). Generally, these differences were small and unlikely to be of clinical significance.

Miscellaneous linear measurements

The reliability of non-specific measurements between various defined occlusal landmarks with both sagittal and transverse components was investigated by Bell *et al*. (2003) and Keating *et al*. (2008). These studies described similar levels of consistency with mean discrepancies of 0.14 and 0.27mm reported, respectively. Consequently, combinations of antero-posterior and transverse measurements appear to have similar reliability as purely transverse or sagittal measurements.

Tooth size

Differences in individual tooth size with digital and direct methods have been measured in the mesio-distal and vertical dimension. Tooth size has also been used indirectly to calculate Bolton tooth-size ratios, arch length and tooth size-arch length discrepancy. Generally, minor mean differences in mesio-distal tooth dimension of

0.01 to 0.3 mm were reported overall (Santoro *et al*., 2003; Redlich *et al*., 2008; Goonewardene *et al*., 2008; Watanabe-Kanno *et al*., 2009; Naidu *et al*., 2009; Mangiacapra *et al*., 2009; Horton *et al*., 2010).

Measurement of vertical crown height is likely to be imprecise with identification of a cervical point particularly unreliable. Keating *et al*. (2008) assessed vertical crown heights of premolars and molars using the maximum point of concavity on the labial surface gingival margin as the cervical reference point; a difference in the measurement of canine and molar heights of 0.1mm was detected.

Bolton ratio

Comparison of Bolton tooth size analysis has been performed on digital and plaster models (Tomassetti *et al*., 2001; Stevens *et al*., 2006; Mullen *et al*., 2007; Naidu *et al.*, 2009; Watanabe-Kanno *et al*., 2010). Acceptable agreement between the two methods was demonstrated in all five studies. Stevens *et al*. (2006) described an anterior discrepancy of 0.6mm; however, Mullen *et al*. (2007) reported an overall mean difference of just 0.05mm. An overall mean discrepancy of 0.38mm was determined by Stevens *et al*. (2006) using emodels; Tomassetti *et al*. (2001) found a more significant difference of 1.02 to 1.2mm between direct measurement on plaster models and digital measurement using OrthoCad™. Naidu *et al.* (2009) reported no statistically significant differences between mean Bolton ratios obtained with Digimodels™ and digital calipers, the overall ratios being just 0.18% greater with the digital models (95% CI: –0.42, 0.78%). They found the mean discrepancy for the anterior ratio to be slightly larger (0.43%; 95% CI: -1.11, 0.25), although the difference was also not of statistical significance.

Space analysis, arch length and tooth size-arch length discrepancy (crowding)

Overall arch length, crowding and space analysis were measured in seven studies (Quimby *et al*., 2004; Stevens *et al*., 2006; Redlich *et al*., 2008; Goonewardene *et al*., 2008; Leifert *et al*., 2009; Watanabe-Kanno *et al*., 2010; Abizadeh *et al*., 2012). With respect to arch length, discrepancies between the techniques ranged from 0.19 (Redlich *et al*., 2008) to 1.15mm (Abizadeh *et al*., 2012). The difference between the measurement of crowding obtained with the techniques varied from 0.19mm (Goonewardene *et al*., 2008) to 0.42mm (Leifert *et al*., 2009); however, the mean degree of crowding in each trial did not exceed 4.69mm (Leifert *et al*., 2009) with the arches being spaced in one of the studies (Goonewardene *et al*., 2008).

Irregularity Index

Goonewardene *et al.* (2008) measured the irregularity index in both the maxillary and mandibular arches; identical mean levels of irregularity were calculated with both techniques using OrthoCad^{TM} digital models. However, using emodels^{TM}, Stevens *et al.* reported a significant discrepancy with the digital software underestimating irregularity by 3.7mm.

Inter-arch occlusal features

Agreement between measurement of overjet and overbite has been considered in six studies Santoro *et al*. (2003); Quimby *et al*. (2004); Stevens *et al*. (2006); Watanabe-Kanno *et al*. (2009); Mangiacapra *et al*. (2009) and Abizadeh *et al*. (2012). Quimby *et al*. reported near perfect agreement for both parameters; similarly, Santoro *et al*., Stevens *et al*. and Abizadeh *et al.* showed excellent agreement for overjet measurement. However, significant differences between the techniques were found for measurement of overbite in five studies (Santoro *et al*., 2003); Stevens *et al*., 2006; Watanabe-Kanno *et al*., 2009; Mangiacapra *et al*., 2009; Abizadeh *et al*., 2012). The concordance of measurement of posterior crossbite and centreline discrepancy was confirmed by Stevens *et al*. (2006). Inter-arch features including buccal segment interdigitation, overbite and overjet are also considered as part of occlusal indices including PAR, ICON and American Board of Orthodontics (ABO) scoring.

Occlusal indices

Acceptable concordance with digital and plaster models in relation to the severity of malocclusion using Peer Assessment Rating, ICON and ABO scores has been demonstrated. The agreement between manual and digital measurements was high with respect to both PAR (Mayers *et al*., 2005; Stevens *et al*., 2006) and ICON (Veenema *et al*., 2009). In relation to the ABO score, three studies (Costalos *et al*, 2005; Okunami *et al*., 2007; Hildebrand *et al*., 2008) reported comparisons between the techniques (Table 14). In general, the differences between the measurement methods is low; however, Okunami *et al*. (2007) and Costalos *et al*. (2005) reported a significant discrepancy with respect to occlusal contact and buccolingual inclination scores. Furthermore, Costalos *et al*. (2005) reported a significant difference in arch irregularity. These discrepancies were attributed to limitations pertaining to one software program (OrthoCad ^{TM}); the ABO method of measuring inclination is also difficult to apply to digital models.

Time taken

The difference in the time required to perform a variety of occlusal measurements has been assessed in three disparate studies (Tomassetti *et al*., 2001; Mullen *et al*., 2007; Horton *et al*., 2010). These studies suggest a significant time saving with digital techniques although a significant learning curve and period of adjustment is likely to be required. Relatively minor differences were described by Horton *et al*. (2 minutes) and Mullen *et al*. (1 minute). The approach to digital measurement is also believed to have an impact with manipulation of the model being necessary to perform specific measurements. Differences may also arise in view of software and familiarity with the technique; Mullen *et al*. (2007) used the widely available emodels™. Horton *et al*. (2010) measured time taken to calculate tooth dimensions in isolation and Mullen *et al*. (2007) calculated Bolton tooth size ratios.

Table 13. Summary of results obtained with digital models and plaster models where described.

Study	N+	Measurement	Digital model Mean (SD)	Plaster model Mean (SD)
Transverse dimensions (mm)				
Quimby *et al*. (2004)	1000	Maxillary IMW Maxillary ICW Mandibular IMW Mandibular ICW	54.72 (0.85) 36.04 (0.51) 47.42 (0.52) 26.31 (0.27)	54.43 (0.26) 36.44 (0.26) 47.38 (0.33) 26.65 (0.24)
Keating *et al*. (2008)	60	ICW/IPMW/IMW		
Watanabe-Kanno *et al*. (2009)	30	Maxillary ICW Maxillary IPMW Maxillary IMW Mandibular ICW Mandibular IPMW Mandibular IMW	34.23 (1.78) 34.52 (2.01) 44.83 (2.54) 26.57 (1.57) 28.73 (1.86) 39.66 (2.25)	34.35 (1.78) 34.63 (2.02) 44.99 (2.54) 26.71 (1.58) 28.86 (1.85) 39.78 (2.25)
Mangiacapra *et al*., 2009		Mandibular ICW Mandibular IMW	-	-

Abizadeh *et al*. (2012)		Maxillary ICW Maxillary IMW Mandibular ICW Mandibular IMW	-	-
Miscellaneous linear measurements (mm)				
Bell *et al*. (2003)	176	Various transverse and sagittal measurements	-	-
Keating *et al*. (2008)	60	Y plane: Combined transverse and sagittal dimensions Overall	-	-
Tooth size (mm)				
Santoro *et al*. (2003)	40	Overall mean	-	-
Redlich *et al*. (2008)	90	Maxillary mean Mandibular mean	7.73 (0.1$^{\$}$) 7.1 (0.1$^{\$}$)	7.7 (0.12$^{\$}$) 7.11 (0.1$^{\$}$)
Goonewardene *et al*. (2008)	50	Maxillary overall Mandibular overall	76.1 (3.61) 66.3 (3.22)	74.8 (4) 65.7 (3.55)
Watanabe-Kanno *et al*. (2009)	30	21 26	8.76 (0.63) 9.9 (0.46)	8.94 (0.63) 10.1 (0.46)
Naidu *et al.* (2009)	25	Overall difference	-	-
Mangiacapra *et al*., 2009	200	Overall difference	-	-
Horton *et al*. (2010)	96	Overall difference	-	-
Keating *et al*. (2008)	60	Crown height	-	-

Abizadeh *et al*. (2012)	112	Crown height	-	-
Bolton ratio (mm)				
Tomassetti *et al*. (2001)	66	Anterior Overall	- -	- -
Stevens *et al*. (2006)	360	Anterior Overall	-0.55 (2.00) -0.75 (2.64)	-0.51 (1.80) -0.37 (2.20)
Mullen *et al*. (2007)	30	Overall	-	-
Naidu *et al.* (2009)	25	Anterior Overall	- -	- -
Watanabe-Kanno *et al*. (2010)	30	Anterior Overall	0.96 (1.73) 1.58 (2.54)	1.3 (1.49) 1.92 (2.18)
Space analysis, arch length and tooth size-arch length discrepancy (crowding) (mm)				
Quimby *et al*. (2004)	1000	Maxillary space available Maxillary space required Mandibular space available Mandibular space required	74.87 (1.06) 73.69 (0.93) 65.71 (0.74) 63.85 (0.86)	73.58 (0.45) 73 (0.37) 64.02 (0.43) 63.24 (0.49)
Stevens *et al*. (2006)	360	Maxillary arch length Mandibular arch length	94.58 (5.25) 87.16 (5.44)	94.78 (5.33) 86.96 (5.17)
Mullen *et al*. (2007)	30	Maxillary arch length	-	-

		Mandibular arch length	-	-
Redlich *et al*. (2008)	90	Maxillary arch length	-	-
		Mandibular arch length	-	-
		Maxillary crowding	73.45 (1.26)	73.64 (1.64)
		Mandibular crowding	64.18 (1.29)	64.88 (1.22)
Goonewardene *et al*. (2008)	50	Maxillary arch length	1.41 (0.91)	1.77 (1.01)
		Mandibular arch length	0.3 (0.92)	0.71 (0.92)
		Maxillary crowding	75.8 (4.32)	74.8 (4.24)
		Mandibular crowding	65.9 (3)	65.1 (3.28)
Leifert *et al*. (2009)	50	Maxillary crowding	4.27 (2.41)	4.69 (2.46)
		Mandibular crowding	3.69 (3)	3.9 (3.09)
Watanabe-Kanno *et al*. (2010)	30	Maxillary arch length	78.66 (3.39)	79.09 (3.43)
		Mandibular arch length	68.51 (2.36)	68.8 (2.44)
Irregularity index (mm)				
Stevens *et al*. (2006)	360	Overall	23.7 (7.81)	20.99 (7.47)
Goonewardene *et al*.	50	Maxillary Mandibular	7.8 (4.89) 7.1 (3.07)	7.8 (5.09) 7.1 (3.19)

(2008)				
Inter-arch occlusal features (mm)				
Stevens *et al*. (2006) Abizadeh *et al*. (2012)	360 112	Centreline Posterior crossbite Anterior crossbite Centreline	1.23 (1.04) 0.75 (1.86) 0.63 (0.98) -	1.32 (1.1) 0.74 (1.84) 0.67 (1.09) -
Santoro *et al*. (2003) Quimby *et al*. (2004) Stevens *et al*. (2006) Watanabe-Kanno *et al*. (2009) Abizadeh *et al*. (2012)	40 1000 360 30 112	Overjet	 1.41 (0.4) 4.91 (2.98) 5.22 (2.24) -	 1.4 (0.21) 4.9 (2.97) 5.43 (2.24) -
Santoro *et al*. (2003) Quimby *et al*. (2004) Stevens *et al*. (2006) Watanabe-Kanno *et al*.	40 1000 360 30	Overbite	 1.45 (0.53) 3.67 (1.82) 3.2 (1.32)	 1.48 (0.3) 3.96 (1.75) 3.51 (1.33)

(2009)				
Mangiacapra *et al*., 2009	200		-	-
Abizadeh *et al*. (2012)	112		-	-
Occlusal indices				
Veenema *et al*. (2009)	60	Total ICON score (Examiner 1)	10.97 (2.47) 4.13 (1.31)	11.47 (2.37) 3.4 (1.07)
Mayers *et al*. (2005)	96	Overall PAR score	27.25 (11.49)	27.35 (12.75)
Stevens *et al*. (2006)	360		25.91 (8.79)	25.08 (9.3)
Time taken (mins.)				
Tomassetti *et al*. (2001)	66	Bolton analysis	5.37 (0.87)	8.06 (0.54)
Mullen *et al*. (2007)	30	Bolton analysis	-	-
Horton *et al*. (2010)	96	Occlusal view technique	-	-

+ Number of determinations

Table 14. Differences between results derived from digital and plaster models.

Study	N+	Measurement	Mean Difference* (P Value, SE or CI)	Average of absolute mean difference* (SD)
Transverse dimensions^ (mm)				
Quimby *et al.* (2004)	1000	Maxillary IMW Maxillary ICW Mandibular IMW Mandibular ICW	0.29 (P < 0.05)^ -0.4 (P < 0.05)^ 0.04 (P < 0.05)^ -0.34 (P < 0.05)^	
Keating *et al.* (2008)	60	ICW/IPMW/IMW	P= 0.765	0.19 (0.12)
Watanabe-Kanno *et al.* (2009)	30	Maxillary ICW Maxillary IPMW Maxillary IMW Mandibular ICW Mandibular IPMW Mandibular IMW	-0.12 (P<0.001)^ -0.11 (P<0.001)^ -0.16 (P<0.001)^ -0.14 (P<0.001)^ -0.13 (P<0.001)^ -0.12 (P<0.001)^	
Mangiacapra *et al.* (2009)	200	Mandibular ICW Mandibular IMW	P= 0.11 P= 0.24	
Abizadeh *et al.* (2012)	112	Maxillary ICW Maxillary IMW Mandibular ICW Mandibular IMW	0.14 (P<0.001)^ 0.15 (P=0.014)^ -0.17 (P<0.001)^ 0.07 (P=0.495)	
Miscellaneous linear measurements (mm)				
Bell *et al.* (2003)	176	Various transverse and sagittal measurements	P>0.05	0.27 (0.06)
Keating *et al.* (2008)	60	Y plane: Combined transverse and sagittal dimensions Overall	P= 0.501 P= 0.237	0.14 (0.09) 0.14 (0.1)

Tooth size (mm)				
Santoro *et al*. (2003)	40	Overall mean	P<0.01^	-0.252
Redlich *et al*. (2008)	90	Maxillary mean Mandibular mean	0.03 (P > 0.05)^ -0.01 (P < 0.05)	
Goonewardene *et al*. (2008)	50	Maxillary overall Mandibular overall	1.3 0.6	
Watanabe-Kanno *et al*. (2009)	30	21 26	-0.18 (P= 0.6) -0.2 (P<0.001)^	
Naidu *et al.* (2009)	125	Overall difference	-0.08 (95% CI: 0.05, 0.12 mm)^	
Mangiacapra *et al*. (2009)	200	41 46	P= 0.39 P= 0.4	
Horton *et al*. (2010)	96	Overall difference	1.163 (0.115 per tooth)	
Keating *et al*. (2008)	60	Crown height	0.03 (P=0.218)	0.1 (0.07)
Abizadeh *et al*. (2012)	112	Crown height (UL1)	0.53 (P<0.001)^	
Bolton ratio (mm)				
Tomassetti *et al*. (2001)	66	Anterior Overall	1.02 (P= 0.243) 1.2 (P= 0.718)	
Stevens *et al*. (2006)	360	Anterior Overall	-0.04 (P= 0.790) -0.38 (P=0.084)	0.60 (0.38) 0.92 (0.58)
Mullen *et al*. (2007)	30	Overall	-0.05 (SE, 1.87; P = 0.86)	

Naidu *et al*. (2009)	125	Overall Anterior	0.43% (95% CI: -1.11, 0.25) -0.18% (95% CI: –0.42, 0.78%)	
Watanabe-Kanno *et al*. (2010)	30	Overall Anterior	P= 0.1 P=0.04^	
Space analysis, arch length and tooth size-arch length discrepancy (crowding) (mm)				
Quimby *et al*. (2004)	1000	Maxillary space available Maxillary space required Mandibular space available Mandibular space required	0.29 (P < 0.05)^ 0.69 (P < 0.05)^ 1.69 (P < 0.05)^ 0.61 (P < 0.05)^	
Stevens *et al*. (2006)	360	Maxillary arch length Mandibular arch length	-0.20 (P= 0.226) 0.20 (P= 0.256)	0.69 (0.43) 0.65 (0.55)
Mullen *et al*. (2007)	30	Maxillary arch length Mandibular arch length	1.47 (SE, 1.55; P < 0.0001)^ 1.5 (SE, 1.36; P < 0.0001)^	
Redlich *et al*. (2008)	90	Maxillary arch length Mandibular arch length	-0.19 (P > 0.05)^ -0.7 (P > 0.05)^	

		Maxillary crowding Mandibular crowding	-0.26 (P > 0.05)^ -0.41 (P> 0.05)^	
Goonewardene *et al*. (2008)	50	Maxillary arch length Mandibular arch length Maxillary crowding Mandibular crowding	1.0 (P< 0.001)^ 0.8 (P = 0.007)^ -0.19 (SE= 0.219; P= 0.38) 1.19 (SE= 0.23; P<0.000)^	
Leifert *et al*. (2009)	50	Maxillary crowding Mandibular crowding	-0.424 (SE= 0.16; P= 0.01) -0.212 (SE= 0.23; P= 0.364)	
Watanabe-Kanno *et al*. (2010)	30	Maxillary arch length Mandibular arch length	0.43 (P=0.36) 0.29 (P<0.001)^	
Abizadeh *et al*. (2012)	112	Maxillary arch length Mandibular arch length	1.15 (P<0.001)^ 0.5 (P=0.004)^	
Irregularity index (mm)				
Stevens *et al*. (2006)	360	Overall	2.71 (P<0.001)^	3.7 (3.05)
Goonewardene *et al*. (2008)	50	Maxillary Mandibular	0.0 (P= 0.73) 0.0 (P= 0.13)	
Inter-arch occlusal features (mm)				

Stevens *et al*. (2006)	360	Centreline Posterior crossbite Anterior crossbite	-0.1 (P=0.30) 0.01 (P=0.75) -0.03 (P=0.59)	0.34 (0.28) 0.04 (0.12)
Abizadeh *et al*. (2012)	112	Centreline	0.11 (P=0.2)	0.15 (0.26)
Santoro *et al*. (2003)	40	Overjet	P= 0.98	-0.00987
Quimby *et al*. (2004)	1000		0.01 (P > 0.05)	
Stevens *et al*. (2006)	360		0.01 (P=0.88)	0.33 (0.21)
Watanabe-Kanno *et al*. (2009)	30		-0.31 (P<0.001)^	
Abizadeh *et al*. (2012)	112		-0.01 (P=0.872)	
Santoro *et al*. (2003)	40	Overbite	P= 0.0124^	-0.4901
Quimby *et al*. (2004)	1000		-0.03 (P> 0.05)	
Stevens *et al*. (2006)	360		-0.3 (P=0.001)^	0.38 (0.27)
Watanabe-Kanno *et al*. (2009)	30		-0.21 (P<0.001)^	
Mangiacapra *et al*., 2009	200		P<0.001^	

Abizadeh *et al*. (2012)	112		0.67 (P<0.001)^	
Occlusal indices				
Veenema *et al*. (2009)	60	Total ICON score (Examiner 1)	-0.5 0.73 (P< 0.01)	
Mayers *et al*. (2005)	96	Overall PAR score	-0.1 (ICC= 0.96-0.98)	
Stevens *et al*. (2006)	360		0.83 (P=0.128)	2.11 (1.62)
Time taken (mins.)				
Tomassetti *et al*. (2001)	66	Bolton analysis	-2.69^	
Mullen *et al*. (2007)	30	Bolton analysis	P< 0.001^	-65.6 sec (47)
Horton *et al*. (2010)	96	Occlusal view technique	-2.02^	

- Negative values represent smaller values on digital models.
- ^ Significant difference or lack of agreement between plaster and digital techniques

Table 15. Summary of American Board of Orthodontics scoring.

	Costalos *et al.* (2005) (n=24)			Okunami *et al.* (2007) (n=30)		Hildebrand *et al.* (2008) (n=36)	
Measurement technique/ difference	Digital Mean (SD)	Plaster Mean (SD)	P value	Mean diff.	P value	Mean diff. (SD)	P value
Alignment	5.42 (3.11)	7.75 (3.89)	<0.0001	0.23	0.34	0.61 (0.8)	<0.01
Marginal ridges	3.67 (2.48)	4 (2.6)	0.4694	0.03	0.837	0.28 (0.57)	0.11
Inclination	5.67 (1.81)	6.71 (3.06)	0.0507	n/a	n/a	0.28 (0.51)	0.571
Occlusal contacts	6.54 (4.24)	5.33 (5.31)	0.2169	-4.53	0.000	1.89 (2.48)	0.021
Occlusal relationships	1.83 (1.97)	2.17 (2.63)	0.3567	-0.5	0.023	0.11 (0.4)	0.422
Overjet	6.25 (3.42)	4.67 (2.75)	0.1077	-0.37	0.1	3.94 (2.65)	<0.001
Interproximal contacts	0.29 (0.62)	0.75 (1.22)	0.0613	-0.13	0.102	0.03 (0.17)	0.324
Overall	29.67 (9.29)	31.17 (10.47)	0.3467	-5.07	0.000	9 (5.54)	<0.01

5.4 Discussion

Earlier research has confirmed that digital software is capable of faithfully reproducing dental features with a high degree of accuracy (Motohashi and Kuroda, 1999; Kusnoto and Evans, 2002). This research was omitted from this review, as our main focus was to ascertain whether digital models offer a valid and clinically useful alternative to plaster models.

The application of digital models in orthodontic practices has increased steadily with 18 per cent of surveyed practitioners reporting usage in a recent survey in the United States (Keim *et al*., 2008). This development has been prompted by a range of perceived advantages including reduced storage requirements; rapid access to digital information; easy transfer of data; versatility; and financial savings. This systematic review confirms that these proven advantages occur without significant compromise to the reliability of occlusal information.

To analyse the validity of digital models, plaster models were chosen as a reference standard in this review as direct measurement is performed on plaster models with rulers or calipers routinely in orthodontic offices and for research purposes. However, direct measurement on plaster models is inevitably associated with some degree of inaccuracy. To produce a more accurate 'gold standard', researchers have developed artificial models permitting more accurate measurement (Quimby *et al*., 2004) or have compared measurements between artificial structures of known dimension (Brusco *et al*., 2007). Generally, digital models have shown a high degree of accuracy using these techniques (Mullen *et al*., 2007). Much of the error of the measurement technique is likely to reside in point identification rather than being related purely to the measuring device or software. Therefore, with enhancement of direct digital superimposition techniques and digital point recognition, digital modelling may replace plaster models as the 'gold standard'.

Evidence for the validity of digital models as an alternative to plaster models is accumulating. However, the methodological quality of studies included in this review was variable. In particular, description of the sample population was inadequate. Furthermore, separate impressions were used to fabricated digital and plaster models in six of the included studies. Differences in the impressions and casting processes may therefore have contributed to some of the inconsistency reported in these trials (Santoro *et al*., 2003; Quimby *et al*., 2004; Mayers *et al*., 2005; Stevens *et al*., 2006; Naidu *et al*., 2009; Mangiacapra *et al*., 2009). Complete data on the absolute differences between the techniques including confidence intervals and standard errors was also rarely reported. Further studies in this area should refer to QUADAS guidelines (Whiting *et al*., 2003) and would benefit from clear reporting of the patient sample on which the models are based and independent interpretation of results.

This systematic review involved assessment of publications from English language and non-English language databases. Unpublished data was also searched. Consequently, it was felt that most data have been accessed. Where possible complete results were obtained from these studies. Studies were excluded if there was a time lag between taking the impressions and pouring study models, where artificial occlusal setups were used and when models were marked before measurement. However, although not considered formally in this review, the results of these studies appeared to be in general agreement with those of the included research studies.

Overall, the mean discrepancy between measurement based on digital and plaster models was low. The differences were considered in all studies to be clinically insignificant. This finding has been corroborated by studies demonstrating excellent concordance of treatment planning decisions based on digital and plaster models (Rheude *et al*., 2005; Whetten *et al*., 2006). Replacement of plaster with digital models resulted in diagnostic changes in 13%, translating into alteration of the treatment plan in just 6% of cases (Rheude *et al*., 2005). This discrepancy is in keeping with research highlighting inconsistency in orthodontic planning decisions by the same and different clinicians, irrespective of differences in records available (Lee *et al*., 1999; Baumrind *et al*., 1996; Ribareski *et al*., 1996).

A further potential advantage of digital models lies in the ability to measure tooth position in three dimensions. In particular, measurement of inclination of individual teeth on plaster models is unreliable and cumbersome. However, digital models may be manipulated and sectioned to analyse specific teeth and permit estimation of long axis position. Furthermore, three-dimensional mapping of tooth movement may be possible by superimposing dental changes on stable reference structures with use of non-destructive digital manipulation and sectioning techniques.

5.5 Conclusions

Digital models offer a high degree of validity when compared to direct measurement on plaster models; differences between the approaches are likely to be clinically acceptable.

CHAPTER 6. DIGITAL MEASUREMENT OF TRANSVERSE ARCH DIMENSIONS AND DEVELOPMENT OF A REPEATABLE TECHNIQUE TO MEASURE INCLINATION CHANGES ON DIGITAL MODELS.

The proposed measurement technique to be used in the randomised controlled trial was initially to be piloted on a separate sample of pre- and post-treatment models.

6.1 Sample

A random sample was derived from pre- and post-treatment models of patients undergoing comprehensive Orthodontic treatment in the Department of Orthodontics at the Royal London Dental Institute and Kent and Canterbury Hospital.

A sample size calculation was performed in which a difference of 0.5mm between the techniques to measure transverse dimensional changes was considered clinically significant. Based on the findings of Bell *et al.* (2003) a total of 20 sets of models were required to demonstrate a clinically meaningful difference between the respective groups with a power of 90% and alpha of 0.05.

The following selection criteria were met by the sample: (1) 16 years old and above at commencement of treatment, (2) complete permanent dentition from second molar to second molar, (3) presence of a malocclusion, (4) high-quality models with clear palatal anatomy, and (5) treated on a non-extraction basis. Exclusion criteria included: the presence of abnormal crown morphology, occlusal wear, and caries or large restorations prone to alteration of dimensions during the course of treatment. The models represented a wide spectrum of malocclusion types before treatment: Class I incisor relationship (n=7), Class II division 1 (n=7), Class II division 2 (n=2) and Class III incisor relationships (n=4).

6.2 Materials and Methods

The gypsum reference models of both arches of each patient were taken and sent to Electronic Study Models^{TM} (ESM^{TM}, Dublin, Ireland) for digital conversion using the R250 Scanner (3Shape^{TM}) comprising high resolution, charged coupled device (CCD) cameras, a laser projector and articulating table. The generation of the digital models involves the initial scan producing point clouds with a resolution of 0.2mm.

Thereafter, clouds are converted into triangles that may undergo further alteration to incorporate curvature and improve surface detail.

Both plaster and digital models were based on the same stone model in order to generate identical measurements. The digital models were viewed and measured with the proprietary software, using a magnifying function (Orthoanalyzer™, 3Shape, Denmark).

6.3 Assessment of linear dimensional changes

All dimensions were recorded on both pre- and post-treatment models using both manual and digital techniques. The manual technique represented the gold standard allowing assessment of the validity of the digital technique. Manual measurements were undertaken on plaster models directly using digital callipers (150mm ISO 9001 electronic calliper, Tesa Technology, Renens, Switzerland) to a resolution of 0.01 mm. Each plaster model was numbered sequentially. Digital representations of these models were stored using this number. Anatomic landmarks were unmarked and models were measured as serial pairs, with both pre-and post-treatment models measured together.

The digital calliper was used to measure transverse dimensions in both arches (Figure 12) with the callipers perpendicular to the occlusal plane.

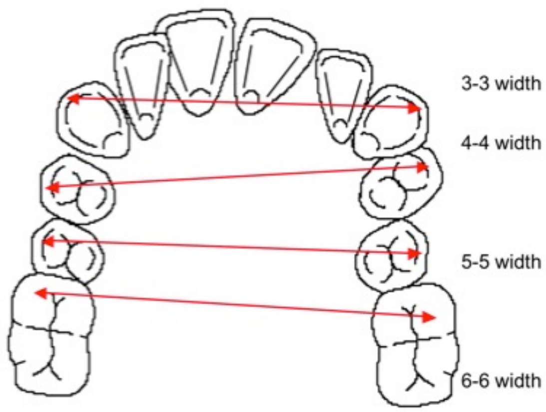


Figure 12. Maxillary transverse arch dimensions.

• 3-3 widths: Inter-canine width was the distance between the canine cusp tips.

• 4-4 widths: Inter-first premolar width was the distance between the buccal cusp tips of both first premolars.

• 5-5 widths: Inter-second premolar width was the distance between the buccal cusp tips of both second premolars.

• 6-6 widths: Inter-molar width was the distance between the mesiobuccal cusp tips of both first molars.

In the presence of wear facets, the midpoint of the point of confluence of the cuspal inclines was estimated to represent the cusp tip. Measurements were made in duplicate and the average value taken to represent the dimension under investigation. Measurements were again made consecutively on each subject's study model (Vaden *et al*., 1997).

The corresponding points were also identified using the digital models and readings were obtained using Orthoanalyzer^{TM} software. To determine the reproducibility of digital linear measurements, digital measurements were performed on two occasions on both pre-and post-treatment models. Models were measured at random, with models unmarked with an interval of two weeks between readings. Differences between the repeated measurements were assessed using Bland and Altman's technique (See 6.5 Statistical Methods).

6.4 Assessment of dental inclination changes in the buccal segments

The second part of the validation study involved assessment of the reproducibility of measurement of dental inclination in the maxillary buccal segments, using a novel technique on digital models. To improve the validity and reproducibility of estimation of the long axis of the teeth, acrylic jigs (PolyMethyl Methacrylate) with a flat upper surface were fabricated. Initially, a machined, customised, transferable acrylic cap was fitted to the maxillary right first permanent molar and central incisor prior to digital scanning (3Shape R700^{TM} Scanner) of both pre- and post-treatment models.

The jigs were fabricated from opaque white PolyMethyl Methacrylate to facilitate scanning. The acrylic extended approximately 5mm above the palatal and occlusal surfaces with some projection onto the buccal surface to withstand rotation of the model during the scanning process. The acrylic jigs were covered with an opaque sealer to prevent light penetration and involution of the jig on the resultant image; stickers were added to the upper surface for the same reason while preserving the flat surface. Prior to fabrication, marked occlusal fissures were blocked out with wax to permit a reproducible fit.

Superimposition of pre-and post-treatment models was piloted using a best-fit method on palatal anatomy by identifying specific points of prominent rugae bilaterally and by mapping areas of similarity in the anterior region of the hard palate producing a mushroom-shaped palatal region on both models (Figure 13). These areas were subsequently registered on each other. Superimposition of the digital scans was performed with the Orthoanalyzer 3D™ software (3Shape), and a preliminary assessment of its accuracy was made. Orthoanalyzer 3D™ software (3Shape) was used to estimate the change in the bucco-lingual orientation of the maxillary first molar by virtual sectioning of the maxillary model and measurement of the angular change in the flat upper surface of the acrylic jig.

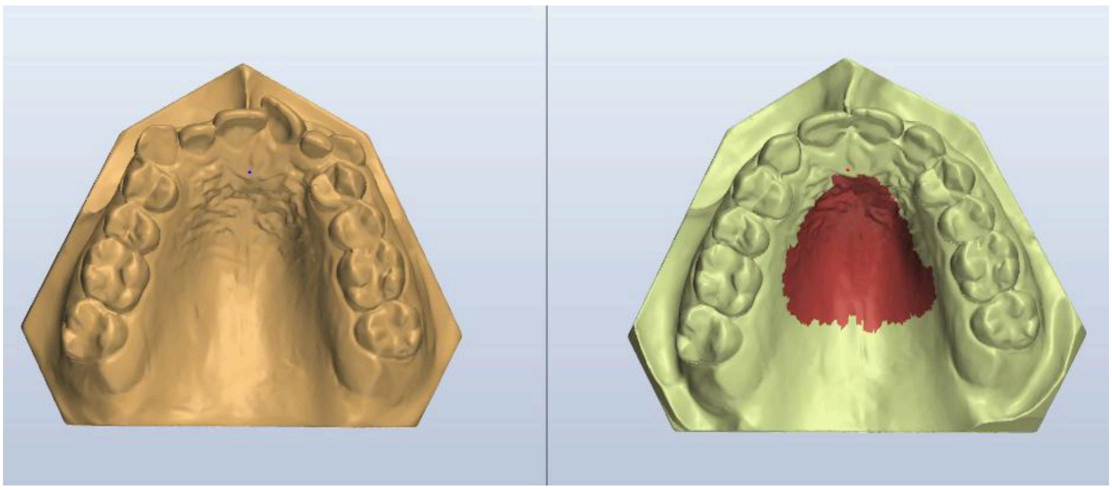


Figure 13. Palatal superimposition technique.

To determine the intra-examiner repeatability of the assessment of inclination changes, readings were undertaken on two occasions on both pre-and post-treatment digital models. Poor agreement was found between sequential measurements of inclination changes. This discrepancy was attributed to inaccurate superimposition on the palate. Consequently, this technique was modified to omit the palatal rugae.

The modified technique involved placement of transferable acrylic jigs on the maxillary first molars bilaterally on both pre- and post-treatment models. The caps fitted snugly on both first permanent molars (Figure 14).

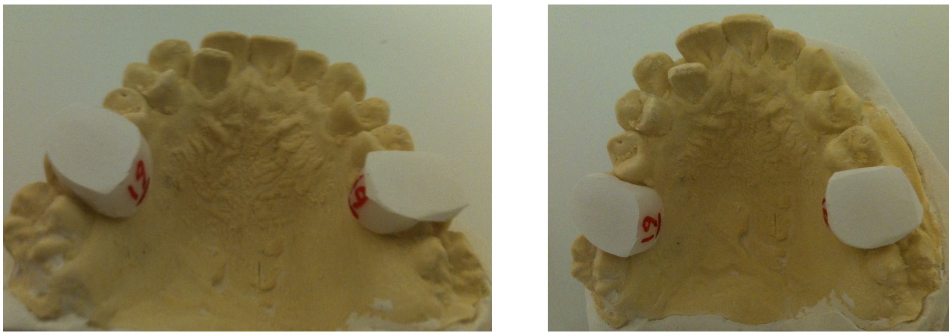


Figure 14. Modified technique with acrylic caps on maxillary first molars.

While this method would not permit measurement of inclination changes of individual teeth, it would be capable of detecting the total bucco-lingual inclination change occurring across the first molars (Figure 15 a-d). Measurements were performed using a splicing function with Orthoanalyzer 3D™ software (3Shape) viewing the virtual models from front or rear views, whichever was felt to be clearest. The orientation in which the model was measured was recorded and this view was maintained during measurement of both pre- and post-treatment models.

In addition, ten models were also scanned following removal and replacement of the jigs on the first molars. This permitted both assessment of the reproducibility of the measurement technique and the fit and placement of the jigs. The reproducibility of this technique was assessed by repeating the measurements in a random order two weeks subsequent to initial readings. An Electronic Study Models (ESM)™ engineer coded all digital representations.

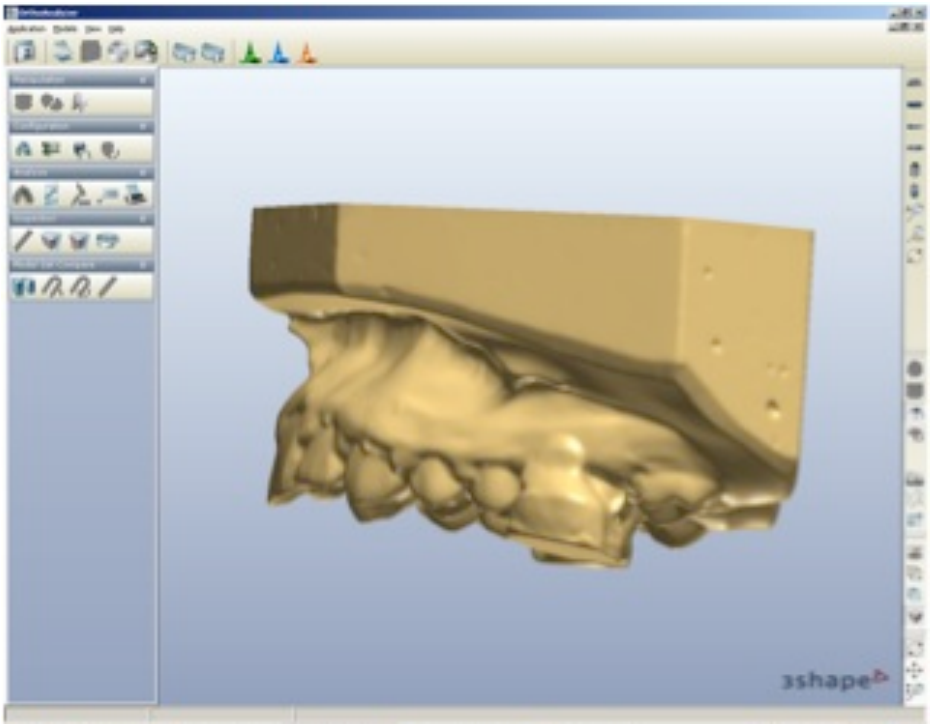


Figure 15a. Digital model with acrylic caps on maxillary molars opened in Orthoanalyzer™.

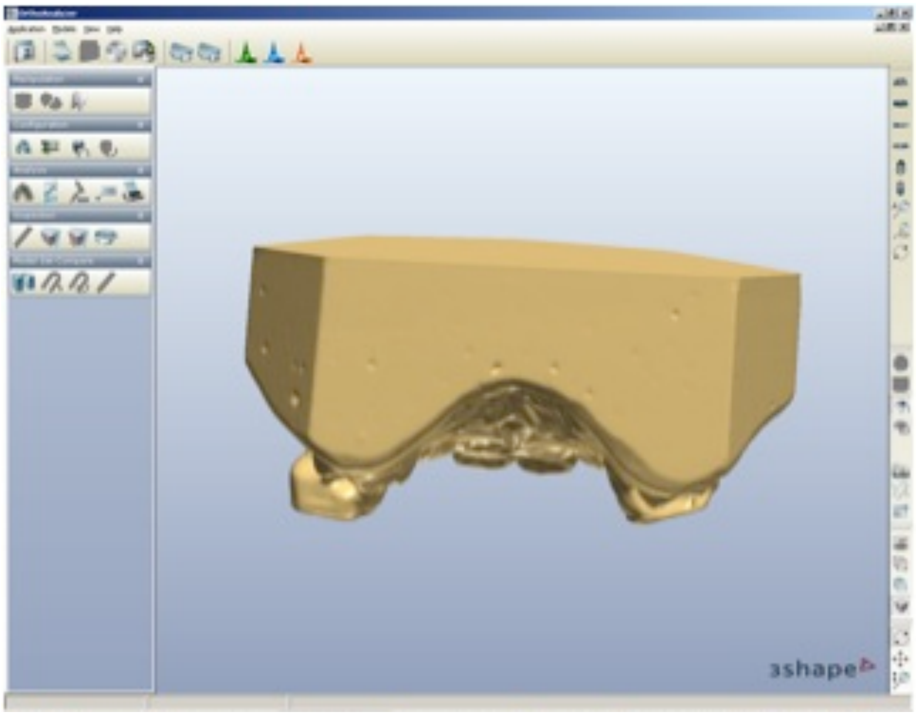


Figure 15b. Rear view of digital model selected.

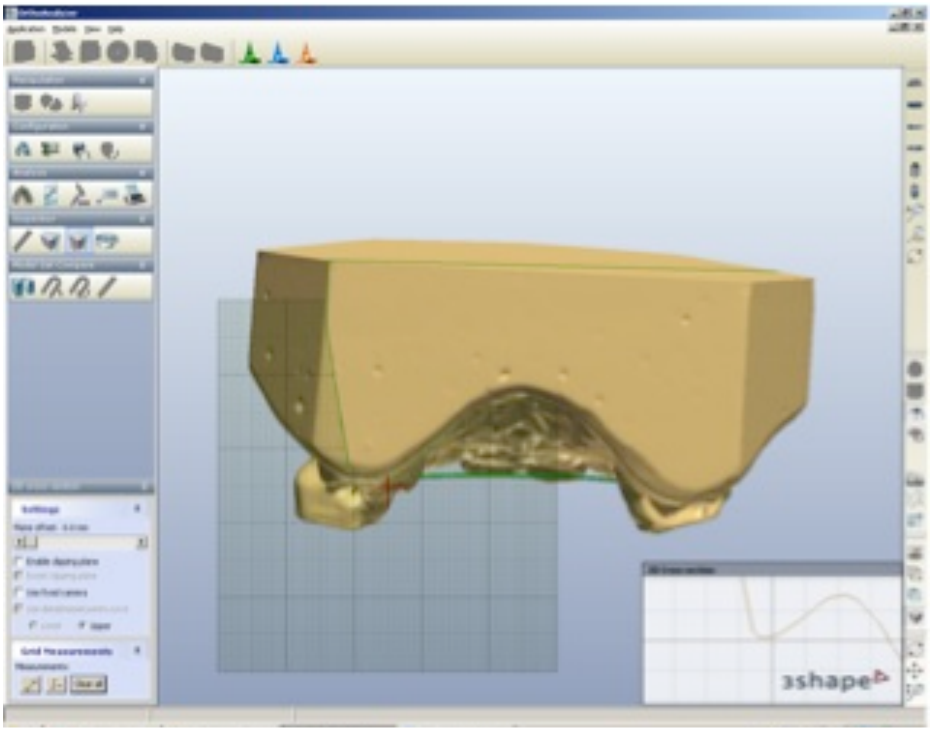


Figure 15c. Measurement tool selected.

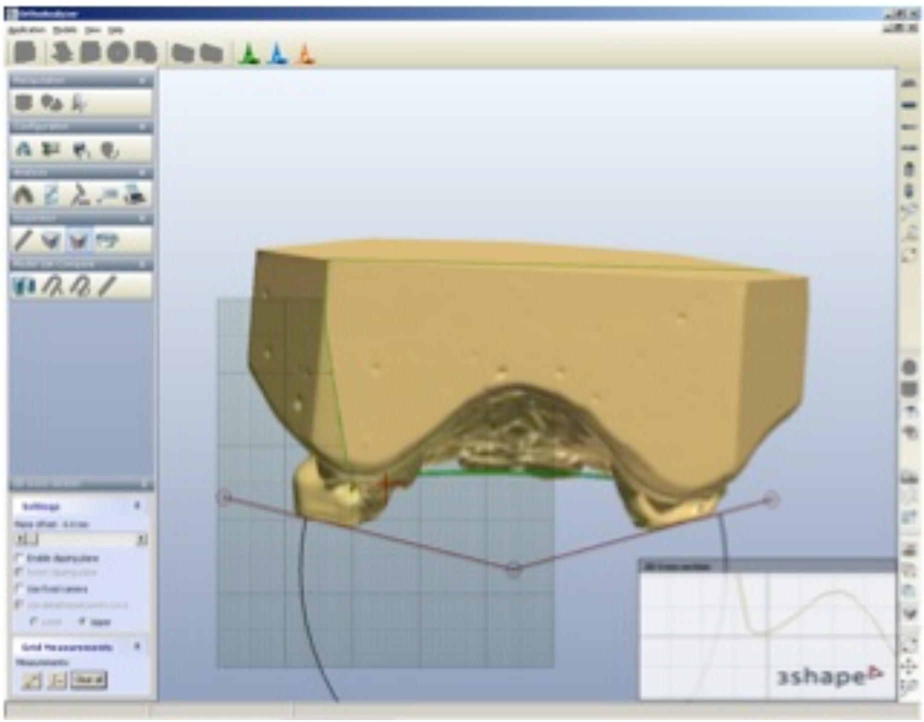


Figure 15d. Angular measurement being performed.

6.5 Error of the method

Two main types of error are likely to have occurred during the measurement process: random and systematic (Houston, 1983). Random error arises in an unpredictable manner and is normally distributed around the true value. These errors can amplify natural variability of measurements and thus may obscure real differences between groups.

Systematic error represents error within the system or bias, resulting in consistently higher or lower values than the true value. If this error remains constant throughout the validation study, it will not affect the trend in the results. If bias alters with time then trends may be masked.

Sources of error in this study

Error may stem predominantly from problems related to measurement techniques, although some inaccuracy may also be related to the measurement devices and the records used. At the stage of impression taking and study cast preparation, inaccuracy may be introduced due to tear and distortion of the alginate impression material. However, the magnitude of error related to this problem is likely to be limited and of little relevance (O'Brien *et al.*, 1990).

Measuring devices

- ESM digital scanner and Orthoanalyzer software. The validity of orthodontic measurements on digital models has variously been confirmed by measuring objects of known dimension and comparing readings to those derived from direct measurement of plaster models (Commer *et al.*, 2000; Sohmura *et al.*, 2000; Kusnoto and Evans, 2002). In the present study, the validity of combined use of the scanner and software for recording linear measurements was assessed by comparing readings obtained to direct measurement using digital callipers.

- Digital callipers. The digital callipers (150mm ISO 9001 electronic calliper, Tesa Technology, Renens, Switzerland) measured to a resolution of 0.01mm. The reproducibility of the calliper measurement was examined subsequent to familiarisation with the measuring technique by measuring the distance between two pinpoints made in gypsum stone. The device was found to be reproducible to ± 0.09 mm. Consequently, the error inherent in the devices themselves is likely to be outweighed by operator error.

Measurement techniques

Minor variations in the use of measuring instruments may produce measurement error. This form of error is usually random in nature although systematic error may be introduced with increasing familiarity.

Inclination changes: The validity and reproducibility of measurement of inclination changes may be affected by the accuracy and repeatability of the placement of the acrylic jigs on the first molars. To assess this 10 models were scanned on two occasions following removal and replacement of the same acrylic cap on the right first molar. The angular reading between tangents to the occlusal surfaces of the right and left jigs was measured.

6.6 Statistical Methods

Data analysis was performed with software (SPSS for Windows, SPSS, New York, NY, USA) with a pre-specified level of statistical significance of $p < .05$.

The reliability of the measures used in the validation study was assessed using a technique described by Bland and Altman (1986). Descriptive statistics were used to compare the measurements obtained with each technique. Outcomes were measured on a continuous scale. Therefore, the agreement between any pair of measurements was assessed using the Bland-Altman limits of agreement method measuring the size of differences between pairs of values that are likely to occur. The measure is obtained by first calculating the difference between the two values for each observation. The 95% limits of agreement, within which 95% of all differences between values should occur, are then calculated as follows:

Mean difference +/- 1.96*(standard deviation of differences)

6.7 Results

6.7.1 Reproducibility of manual measurement of transverse arch dimensions

The repeatability of the manual measurements using the digital calipers was assessed using the limits of agreement method (Bland and Altman, 1986; Table 16). The mean difference between the two sets of measurements was small (0.00-0.83mm). The 95% limits of agreement were within 2mm for all measurements with the exception of maxillary inter-molar width.

Table 16. Reproducibility of measurement of transverse dimensions using the manual measurement technique.

Time	Outcome	Mean difference (mm)	SD difference (mm)	95% Bland-Altman limits
Pre-treatment	MxIMW	0.02	0.86	-1.67, 1.71
	MxIPMW2	-0.29	0.59	-1.45, 0.86
	MxIPMW1	-0.21	0.65	-1.49, 1.06
	MxICW	-0.29	0.65	-1.56, 0.99
	MnIMW	0.28	0.76	-1.20, 1.76
	MnIMPW2	0.19	0.46	-0.72, 1.10
	MnIPMW1	-0.06	0.61	-1.26, 1.14
	MnICW	-0.10	0.69	-1.45, 1.25
Post-treatment	MxIMW	0.83	1.59	-2.28, 3.93
	MxIPMW2	0.00	0.83	-1.62, 1.62
	MxIPMW1	-0.12	0.63	-1.36, 1.12
	MxICW	0.04	0.73	-1.39, 1.46
	MnIMW	0.56	0.69	-0.79, 1.91
	MnIMPW2	0.20	0.74	-1.26, 1.65
	MnIPMW1	-0.07	1.10	-2.23, 2.10
	MnICW	0.13	0.69	-1.18, 1.44

6.7.2 Reproducibility of digital measurement of transverse arch dimensions

The Bland-Altman method was also used to examine agreement between the repeated measurements made using the digital method. These results are summarised below (Table 17).

Table 17. Reproducibility of measurement of transverse dimensions using the digital measurement technique.

Time	Outcome	Mean difference	SD difference	95% Bland-Altman limits
Pre-treatment	MxIMW	0.24	0.93	-1.58, 2.06
	MxIPMW2	0.00	0.47	-0.93, 0.93
	MxIPMW1	-0.33	1.13	-2.54, 1.87
	MxICW	-0.08	0.31	-0.69, 0.54
	MnIMW	-0.11	0.53	-1.16, 0.93
	MnIMPW2	0.05	0.60	-1.12, 1.22
	MnIPMW1	-0.09	0.55	-1.17, 0.99
	MnICW	0.14	0.51	-0.86, 1.14
Post-treatment	MxIMW	0.06	0.39	-0.71, 0.82
	MxIPMW2	0.02	0.43	-0.82, 0.87
	MxIPMW1	-0.06	0.36	-0.77, 0.64
	MxICW	-0.28	0.42	-1.10, 0.55
	MnIMW	-0.02	0.58	-1.17, 1.12
	MnIMPW2	-0.02	0.33	-0.67, 0.63
	MnIPMW1	0.03	0.35	-0.72, 0.66
	MnICW	-0.05	0.50	-1.04, 0.94

The mean difference between the two sets of digital measurements was small (0.00-0.33mm). The 95% limits of agreement were within 2mm for all measurements with the exception of mandibular inter-molar width. The limits of agreement were comparable to those obtained for the manual technique.

6.7.3 Validity of digital measurement of transverse arch dimensions

The validity of digital measurements was assessed by comparison of measurements obtained with this technique with manual readings. The agreement between the first set of manual and digital recordings was therefore assessed using Bland-Altman limits of agreement method (Table 18). The differences were calculated by subtracting the value obtained with the manual technique from that derived digitally; therefore, a positive difference would imply higher values for the digital method.

The results suggested that the mean difference was negligible for almost all outcomes (-0.03 to 0.21mm) confirming the validity of digital measurement of transverse arch dimensions. The exception was the pre-treatment maxillary inter-molar measurement, where the digital method had values that were, on average, 0.7mm lower than those for the manual method.

Table 18. Agreement between manual and digital measurement of transverse intra-arch dimensions.

Time	Outcome	Mean difference	SD difference	95% Bland-Altman limits
Pre-treatment	MxIMW	-0.73	2.18	-5.00, 3.55
	MxIPMW2	-0.14	0.34	-0.80, 0.52
	MxIPMW1	-0.09	0.35	-0.77, 0.58
	MxICW	-0.10	0.34	-0.76, 0.56
	MnIMW	0.09	0.43	-0.75, 0.93
	MnIMPW2	-0.03	0.33	-0.68, 0.62
	MnIPMW1	-0.08	0.32	-0.71, 0.55
	MnICW	-0.13	0.42	-0.95, 0.69
Post-treatment	MxIMW	-0.10	0.93	-1.72, 1.91
	MxIPMW2	-0.04	0.68	-1.30, 1.38
	MxIPMW1	0.04	0.53	-1.09, 1.00
	MxICW	-0.09	0.65	-1.19, 1.37
	MnIMW	0.04	0.39	-0.80, 0.71
	MnIMPW2	-0.03	0.41	-0.78, 0.83
	MnIPMW1	0.21	1.06	-2.29, 1.86
	MnICW	-0.06	0.49	-0.90, 1.02

Negative values denote lower scores with digital models

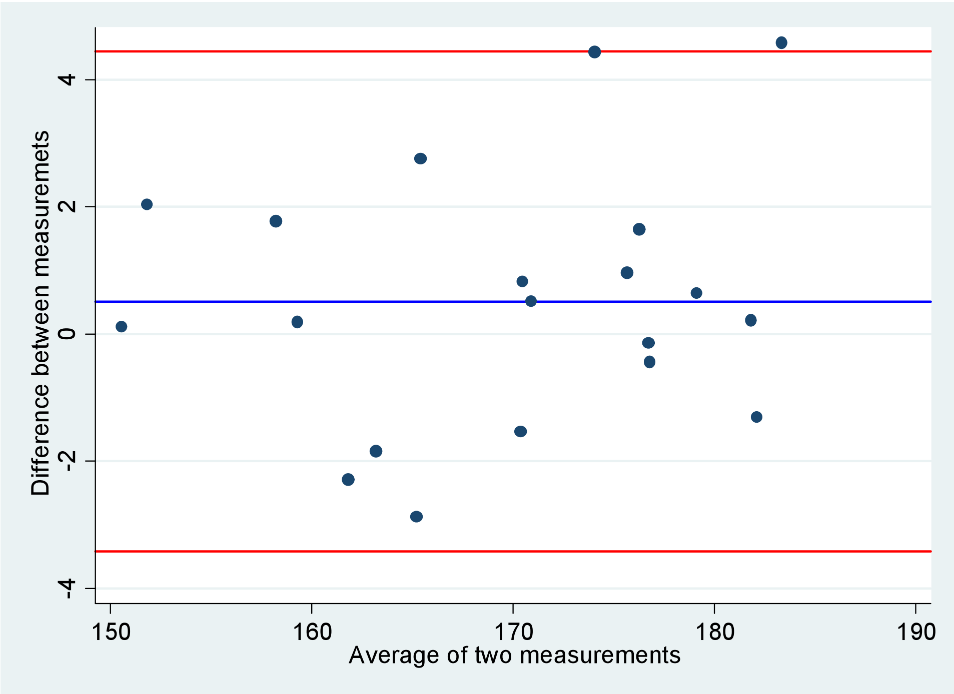
6.7.4 Reproducibility of digital measurement of dental inclination change

An error study of the measurement of maxillary molar inclination change was performed on 20 pairs of models at two-week intervals using the Orthoanalyzer^{TM} software. Bland and Altman's technique was also used to examine agreement between successive measurements of maxillary first molar inclination (Table 19). The majority of repeated measurements of inclination were within 3 to 4 degrees. This was considered to be an acceptable level of agreement. Graphical display of the results indicated that there was a relatively even spread of estimates around the mean value confirming that there was no significant systematic error in the measurement process of both pre-treatment (Figure 16) and post-treatment (Figure

17) models. Repeated measures were generally within four degrees of one another; precision was also unaffected by replacement of the jig suggesting that the fit of the jigs was consistent.

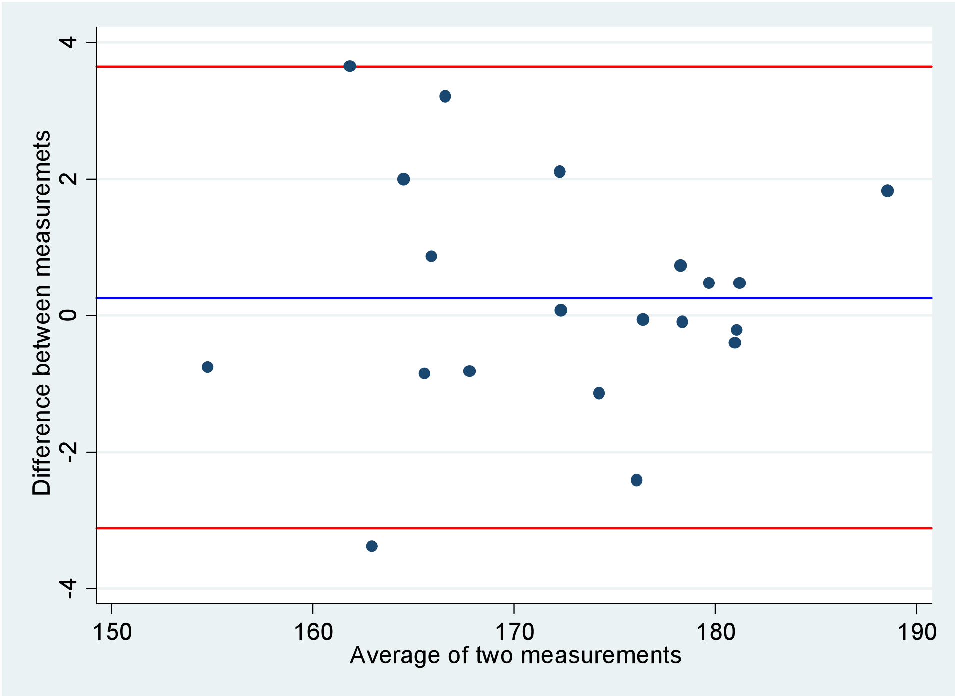
Table 19. Reproducibility of digital technique assessing the inclination of the maxillary first molars.

Dental inclination	**Mean difference (degrees)**	**SD difference**	**95% Bland-Altman limits**
Pre-treatment	0.51	2.01	-3.42, 4.45
Post-treatment	0.26	1.72	-3.12, 3.65



Red lines represent 1.96 x SD of mean difference, blue horizontal line is the mean difference between the techniques.

Figure 16. Graphical display of the reproducibility of the digital technique to assess the inclination of the maxillary first molars on pre-treatment models.



Red lines represent 1.96 x SD of mean difference, blue horizontal line is the mean difference between the techniques.

Figure 17. Graphical display of the reproducibility of the digital technique to assess the inclination of the maxillary first molars on post-treatment models.

6.8 Discussion

The ability to perform valid and reproducible measurement of transverse arch dimensions using digital models has variously been confirmed (Bell *et al*., 2003; Quimby *et al*., 2004; Keating *et al*., 2008; Watanebe-Kanno *et al*., 2009). The findings in the present validation study were in keeping with these studies. However, this investigation is the first to use digital models to measure angular inclination changes in the posterior dentition. The acceptable levels of repeatability in this aspect of the investigation were therefore encouraging.

All transverse maxillary dimensions were recorded in duplicate using digital models. This approach was validated by comparison with the gold standard of direct measurement using digital callipers (150mm ISO 9001 electronic calliper, Tesa Technology, Renens, Switzerland) sensitive to 0.01mm. Inclination changes in the maxillary buccal segments were measured on digital models using a novel approach.

To facilitate this acrylic jigs were made to fit snugly on the relevant teeth permitting stable and reproducible transfer to subsequent models. The superior surface was flat to allow reproducible angular measurement to be undertaken. The chief advantages of this method were simplicity, attenuation of problems related to wear of cusp tips and avoidance of the requirement to gauge the orientation of the long axis of the tooth directly, as the latter can be particularly unreliable.

The likelihood of systematic error was reduced by coding models for identification. None of the teeth on the models were marked prior to the recording process to reduce systematic error (Jones, 1991). Models were measured as serial pairs with measurements made consecutively on each model to limit random error (Houston, 1983; Vaden *et al*., 1997). Consequently, it is unlikely that the results of this validation study were compromised by either random or systematic error.

The validity of orthodontic linear measurement of digital models with respect to direct measurement of plaster models has previously been confirmed and was upheld in the systematic review (Chapter 5). Consequently, the excellent reproducibility and validity of the measurement of transverse dimensions reflected in the narrow Bland-Altman limits were an expected finding. The present findings are compatible with those of Quimby *et al*. (2004) who noted mean differences of no more than 0.4mm for measurement of inter-canine and inter-molar dimensions using OrthoCAD™. Similarly, the mean differences obtained in the present study did not exceed 0.21mm for all but one measurement (pre-treatment maxillary inter-molar width). Likewise Watanebe-Kanno *et al*. (2009) have demonstrated mean differences ranging from 0.11 to 0.19mm for inter-canine, inter-premolar and inter-molar dimensions albeit using separate software (Cecile 3™).

The estimation of inclination changes was significantly more challenging, with estimation of the long axis of a maxillary molar particularly difficult to assess. While the ability to measure inclination changes on digital models is accepted (Costalos *et al*., 2005; Okunami *et al*., 2007), an angular technique involving digital models has not been reported. Previous methods of measuring inclination changes have focused on both manipulation of plaster models (Ciambotti *et al*., 2001; Chung and Goldman, 2003; Franchi *et al*., 2006) and on the use of radiographs (Defraia *et al*., 2008; Ramoglu and Sari, 2010). Techniques involving plaster models typically result in irreversible damage to the model necessitating duplication; no single method has met with widespread use. In addition, use of postero-anterior radiographs to measure buccal segment inclination changes is of questionable validity. More recently CBCT has been used with an associated improvement in validity (Cattaneo *et al.*, 2011). However, this advantage is counterbalanced by the increased radiation dose. Irrespective of the imaging technique used, longitudinal assessment also necessitates repeated radiographic examination, which is unlikely to be sanctioned by ethical review committees due to the additional exposure to ionizing radiation.

An initial technique was piloted in an attempt to gauge inclination changes related to individual teeth by superimposing on potentially stable palatal structures. This technique proved unsuccessful. This failure may relate to difficulty superimposing on structures remote to the area of interest; consequently, minor variation in the potentially stable landmarks was likely to have been amplified in the dental arch. In addition, differences were observed in the palatal topography on sequential models. This may have stemmed from genuine anatomical change, although this is unlikely as the sample was skeletally mature and time intervals between repeated models was relatively short. Further error may have been introduced by the impression and casting techniques, with silicone impression material likely to produce more faithful reproduction of palatal details.

In view of the failure of this method, a modified technique was developed, the scope of which was slightly more limited. This technique would be capable of measuring inclination changes across the arch, with measurement of changes in inter-premolar of inter-molar inclination possible. Similar measures were used to limit systematic and random error with coding of models for identification; use of unmarked models during measurement (Jones, 1991); and measurement as serial pairs (Houston, 1983; Vaden *et al.*, 1997).

The absence of a defined gold standard to gauge inclination changes is problematic when attempting to develop an alternative technique. Previous methods to assess changes in molar inclination have been undertaken by a variety of researchers using a range of techniques and instruments. Kilic *et al.* (2008) using barium sulphate and radiographic imaging of models developed a reproducible technique for assessment of inclination changes of individual molars (Coefficient of reliability: 0.94 to 0.96). The mean magnitude of tipping developing was 13.8 degrees. Similarly, Ciambotti *et al.* (2001) developed a highly reproducible technique to gauge changes in inter-molar angulation with a mean difference of 0.3 degrees (SE 0.559) between repeated measurements. Changes in inter-molar angulation of the order of 6.08 to 11.69 degrees were detected. In addition, Bassarelli *et al*. (2005) used both three-dimensional digitisation and mathematical formulae to estimate inclination changes in the buccal segments with acceptable levels of repeatability. The reliability of this technique is contingent on the absence of occlusal wear of cusp tips during the study period. The authors reported standard errors of 2.59 degrees (SD: 5.03 degrees) and mean changes of up to 6.9 degrees (SD: 4.9 degrees) in inter-premolar angulation. Therefore, the amount of inclination change detailed in these studies could easily be detected using the present methodology.

Franchi *et al*. (2006) developed a further technique involving electromagnetic digitization of cusp tips. This technique may also be subverted by changes in dental morphology particularly due to occlusal wear and is reliant on accurate and reproducible selection of individual points. Unfortunately, the reliability of this technique was not described. However, the mean change in inter-molar angulation (4.33 degrees) exceeded that which can be reliably detected using the present technique.

6.9 Conclusions

The validity of measurement of transverse dimensional changes on digital models was confirmed with respect to manual measurement using digital calipers. A novel technique for measuring inclination changes in the buccal segments was piloted and confirmed to have acceptable repeatability.

CHAPTER 7. RANDOMISED CONTROLLED TRIAL OF ORTHODONTIC TREATMENT WITH THREE FIXED APPLIANCES SYSTEMS.

7.1 Subjects

Ethical approval for a multi-centre randomised controlled trial comparing orthodontic treatment with three fixed appliance systems was obtained from the Cambridgeshire 1 Research Ethics Committee prior to commencement (09/H0304/45, Appendix 3: Page 210). The aim of this research was to assess the magnitude and nature of tooth movements induced by SLBs and CBs during arch alignment and levelling in the maxillary arch.

The study population was drawn from the orthodontic treatment waiting lists in the respective units. An initial diagnosis recommending non-extraction treatment was made by one of the researchers in advance of patients being considered for enrollment into the clinical trial. Those participants satisfying the inclusion criteria were invited to take part in the study prior to commencing treatment. Patients were given an information sheet (Appendix 4: Page 215) and verbal explanation about the content of the study. Those agreeing to participate completed a written consent form (Appendix 5: Page 218).

7.2 Aims and Objectives

The primary objectives were to investigate the influence of appliance type on arch dimensional changes and dental inclination changes. In particular, differences in the changes in maxillary transverse dimensions (inter-canine, inter-premolar and inter-molar widths) arising during arch alignment and levelling with three fixed appliance systems were to be assessed. The differences in the associated inclination changes arising during this treatment phase with the respective appliance systems would also be measured. The null hypothesis to be tested was that treatment with three different fixed appliance systems would result in no difference in transverse dimensional or inclination changes during levelling and alignment.

To facilitate the assessment of molar inclination changes, it was necessary to pilot and confirm acceptable repeatability of a novel technique for measuring dental inclination changes (Chapter 6).

7.3 Design and Setting

The design of the present research was a multicentre, multi-arm parallel study. It was conducted in the United Kingdom in three centres: The Royal London Dental Hospital, East Kent Hospitals NHS Foundation Trust and the Southend NHS Foundation Trust, with equal randomisation to one of three groups. Patients were recruited from August 2009 to April 2011. All three centres are teaching units primarily treating complex malocclusions with an IOTN Dental Health Component of 4 or 5 (Brook and Shaw, 1989).

7.4 Sample size

Based on our group's previous research (Fleming *et al*., 2009a) a minimum of 81 participants (27 in each group) were required with a power of 90 per cent to detect a minimum difference of 1mm (Mean= 44.96; SD= 1mm) between the largest and the smallest mean among the three groups in inter-molar width changes at the 0.05 level of statistical significance. To compensate for attrition of the sample and to enhance statistical power, a further 15 subjects (18.75%) were to be recruited, culminating in a total sample of 96. The power calculation was verified in STATA version 12.1™ (STATA Corporation, College Station, Tx, USA) using the fpower command: One-way ANOVA Power Analysis.

7.5 Selection criteria

The following selection criteria were applied:

Inclusion criteria:

- Young adults aged 16 years and over;
- Fit and well and on no medication;
- In the permanent dentition with maxillary second molars erupted;
- Maxillary arch crowding less than 6mm;
- Amenable to non-extraction treatment in the maxillary arch

Exclusion criteria:

- Cleft lip and palate and other craniofacial anomalies.
- Previous orthodontic treatment;

- Complex medical history and taking medications;
- Congenital absence of teeth in the maxillary arch, other than 3rd molars.

7.6 Randomisation: Sequence generation, allocation concealment and implementation

An unpredictable, stratified subject allocation sequence was generated using an electronic randomisation program. Stratified randomisation was performed for individual centres. Randomisation was carried out in blocks of 12 participants in a ratio of 1:1:1 to ensure relatively even numbers of participants were recruited throughout the trial.

Subsequent to recall from the treatment waiting list and satisfaction of the inclusion criteria, consenting subjects were assigned a unique identification number. This number was documented on the clinical notes and consent forms, allowing assignment to the appropriate treatment group based on the electronic randomisation.

The assignment of each subject was implemented by one of the researchers and concealed from the clinician until the appointment at which the appliance was to be placed using sequentially numbered, opaque and sealed envelopes. Corresponding envelopes were opened after the enrolled participants completed all baseline assessments and were due to commence active treatment.

7.6.1 Blinding

The visibility of the orthodontic appliances precluded blinding of either the operator or the participants to the allocated arm during treatment. However, the outcome assessor and data analysts were kept blinded from the appliance type during data collection and analysis.

7.7 Interventions

Subjects were randomly assigned to one of three groups: the intervention groups having pre-adjusted edgewise treatment with the passive self-ligating pre-adjusted edgewise brackets (Damon Q™, Ormco) or an active self-ligating bracket (InOvation

C^{TM}, GAC) and the comparison group treated with the conventional pre-adjusted edgewise brackets (Ovation^{TM}, GAC).

Participants were treated by 8 operators overall. Self-ligating pre-adjusted edgewise brackets (DamonQ^{TM}, InOvation C^{TM}) with Roth values for tip and torque and 0.022 inch slot were placed in the intervention groups. Pre-adjusted edgewise brackets (Ovation^{TM}) were placed in the comparison group in the maxillary arch according to the random allocation procedure. A 0.013 or 0.014 inch round, copper nickel-titanium archwire (Damon^{TM}, Ormco) of uniform arch form was placed at the first visit in all cases. Attachments were placed on all teeth from first maxillary second molar to second molar. The conventional twin brackets were ligated with elastomeric modules. Areas with marked irregularity in the group with conventional brackets were tied with elastomerics in a figure-of-eight configuration or with stainless steel ligatures to permit complete engagement. Subjects underwent treatment with a pre-determined Damon^{TM} archwire sequence comprising:

- 0.013 or 0.014 inch round CuNiTi;
- 0.014 X 0.025 inch CuNiTi;
- 0.018 X 0.025 inch CuNiTi;
- 0.019 X 0.025 inch Stainless Steel

All wires were of Damon arch form and were not coordinated to the original arch form or dimensions. Archwires were changed after intervals of 10 weeks, 10 weeks, six weeks and eight weeks, respectively, in keeping with the manufacturers recommendations.

In relation to the upper fixed appliance, the archwire was cut distal to the second molar tube; the wire was not cinched distally. No bite planes; palatal arches; quadhelices; palatal expanders; inter maxillary elastics; or headgear to the maxillary arch was used during the study period.

7.8 Protocol deviations

All patients failing an appointment were sent a further appointment. Those wishing to withdraw from the trial were free to do so at any point without affecting continuing care. The relevant records were to be taken at the point of withdrawal from the study.

In cases of appliance breakage, every effort was made for a patient to be seen by a principal operator. However, in certain circumstances the patient was seen by a further investigator with replacement of brackets of the original appliance specification following breakage. If it was deemed impossible to religate a wire of the same dimension, this wire was substituted with a narrower dimension wire within the wire sequence used throughout the study.

7.9 Outcome measures

Final data collection was undertaken a minimum of 34 weeks after treatment commenced. Measured outcomes included:

● Transverse maxillary dimensional changes (inter-canine; inter-premolar and inter-molar widths) arising during alignment and levelling with the three appliance systems,

● Changes in the bucco-palatal inclination of the maxillary first permanent molars and central incisors occurring during levelling and alignment over a minimum of 34 weeks with the three appliances.

7.10 Data collection

Data was derived from analysis of sequential study models including transverse dimensional changes and dental inclination changes and cephalometric angular measurements.

Final data was collected a minimum of 34 weeks after placement of the maxillary pre-adjusted appliance, at which stage a 0.019 X 0.025 inch stainless steel archwire was engaged passively. These data were based on analysis of further maxillary arch impressions and a lateral cephalogram. A Cone Beam CT scan was originally planned for subjects undergoing combined orthodontic-surgical care in order to aid surgical planning. However, this was considered unnecessary during the study as it was felt that it would lead to little additional information to inform planned patient care.

Measurements were undertaken on pre-treatment study models and those obtained after the final maxillary archwire was replaced. Prior to the recording process each model was numbered for identification purposes. Brackets were obscured with wax on post-treatment models. Models were measured as serial pairs (Houston, 1983) with none of the teeth on the models being marked prior to the recording process (Jones, 1991). Measurements were made consecutively on each cast. Cephalograms were obtained before treatment and following completion of arch alignment and leveling, and were subsequently traced.

7.11 Measurement of transverse dimensions and molar inclination

Measurements comprised both data derived from digital models and cephalograms. Transverse dimensions were measured with digital callipers. The measurement technique used is outlined in Section 6.3. Molar inclination was recorded using the technique piloted on digital models and outlined in Chapter 6.

7.12 Cephalometric analysis

Lateral cephalograms taken at the commencement of treatment and at a minimum of 34 weeks after initial appliance placement were digitised and traced. Angular changes in axial inclination of the long axis of the maxillary incisor relative to the maxillary plane (Ui-MxP) were measured by assessing Ui-MxP on both lateral cephalograms. The cephalometric landmarks and planes used in the study are described in Table 20 and presented graphically in Figure 18.

Radiographs were traced and measured as serial pairs (Houston, 1983). Two sets of readings were obtained for each measurement and their values averaged (Houston, 1983). Individual angles were retraced if differences between values exceeded 5 degrees. Maxillary incisor inclination was measured to a tolerance of 0.5 degrees.

Table 20. Cephalometric landmarks, planes and angles, adapted from Daskallogiannakis (2000)

Cephalometric landmark/plane/angle	Definition
Is (Incision superius)	The incisal tip of the crown of the most labially placed maxillary incisor.
Ur	The apex of the maxillary central incisor.
ANS	Anterior nasal spine
PNS	Posterior nasal spine
Maxillary plane (MP)	The plane through the maxillary base by joining points passing through the points ANS and PNS.
Upper incisor axis (UIA)	A line passing through the points Is and Ur.
Ui-MxP (α)	Angle formed by the maxillary central incisor and the maxillary plane.

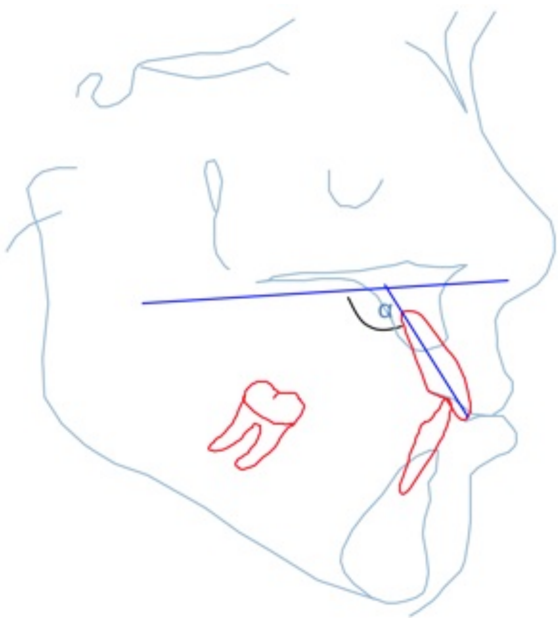


Figure 18. Cephalometric points, planes, lines and angles

7.13 Measurement of crowding

The degree of crowding was recorded on baseline and final models by measuring the combined mesio-distal widths of the teeth from mesial of first molar to mesial of first molar (space required) and subtracting the arch perimeter. The arch perimeter was the sum of the two anterior segments and the two posterior segments (Figure 19).

The measurements were performed with a digital calliper (150mm ISO 9001 electronic calliper, Tesa Technology, Renens, Switzerland) with a resolution of ±0.01mm. The arch was viewed from above and the callipers held parallel to the maxillary occlusal plane. Models were measured as serial pairs.

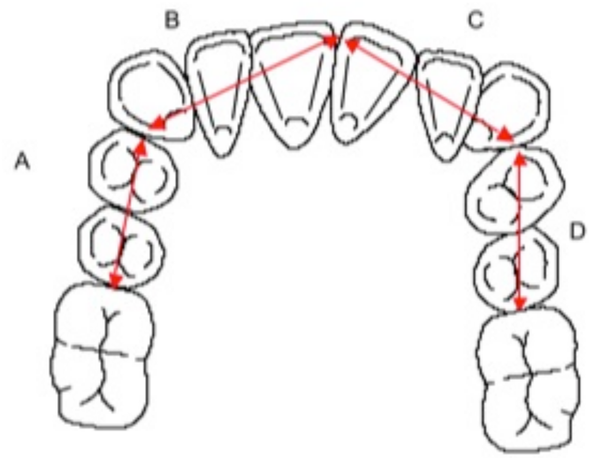


Figure 19. Maxillary arch perimeter= A+B+C+D.

7.14 Minimising error in cephalometric analysis

Systematic error: Each radiograph was to be numbered for identification. The type of appliance in use was not identifiable from the lateral cephalometric view.

Random error: All recordings were to be made under standardised conditions. Two sets of readings were to be obtained for each measurement and their values averaged to reduce random error (Houston, 1983). Outlying measurements with a discrepancy of in excess of 5 degrees between repeated measurements would be repeated. Radiographs were to be measured as serial pairs aiding identification of homologous structures (Houston, 1983).

7.15 Statistical Methods

The reliability of the measures used in the study was examined by assessing agreement between the measurements according to a technique described by Bland and Altman (1986, Chapter 6).

A summary of baseline characteristics of participants in the study was performed in order to ensure that all groups had similar clinical and demographic characteristics at the beginning of the trial. In accordance with the CONSORT guidelines, significance testing for pre-treatment equivalence was not performed, as this is no longer recommended statistical practice (Altman *et al*., 2001).

Analysis of covariance (ANCOVA) was to be used to compare the influence of the three bracket systems on transverse dimensional changes and incisor and buccal segment inclination changes. Separate analyses were conducted for each dimension or outcome of interest. Pre-treatment crowding, and pre-treatment values for incisor inclination or transverse dimensions were treated as covariates in the analysis to account for differences in these potential confounders. An exploratory assessment of the effect of pre-treatment inter-canine dimension on expansion of the maxillary inter-first premolar, inter-second premolar and inter-molar widths was also to be undertaken. Assumptions for linear regression were to be assessed by plotting residuals.

All statistical analyses were conducted with statistical software STATA version 12.1™ (STATA Corporation, College Station, Tx, USA) with a pre-specified level of statistical significance of $p < .05$.

7.16 Results

7.16.1 Response Rate

Overall, one hundred and one participants were recruited from August 2009 to June 2011; of these 96 received one of the interventions. Subjects were evenly distributed between the three groups (Figure 20). Nine of these participants had missing data; however, data were analysed on a per-protocol basis, given that the attrition rate was relatively minor and unlikely to be attributable to bracket design.

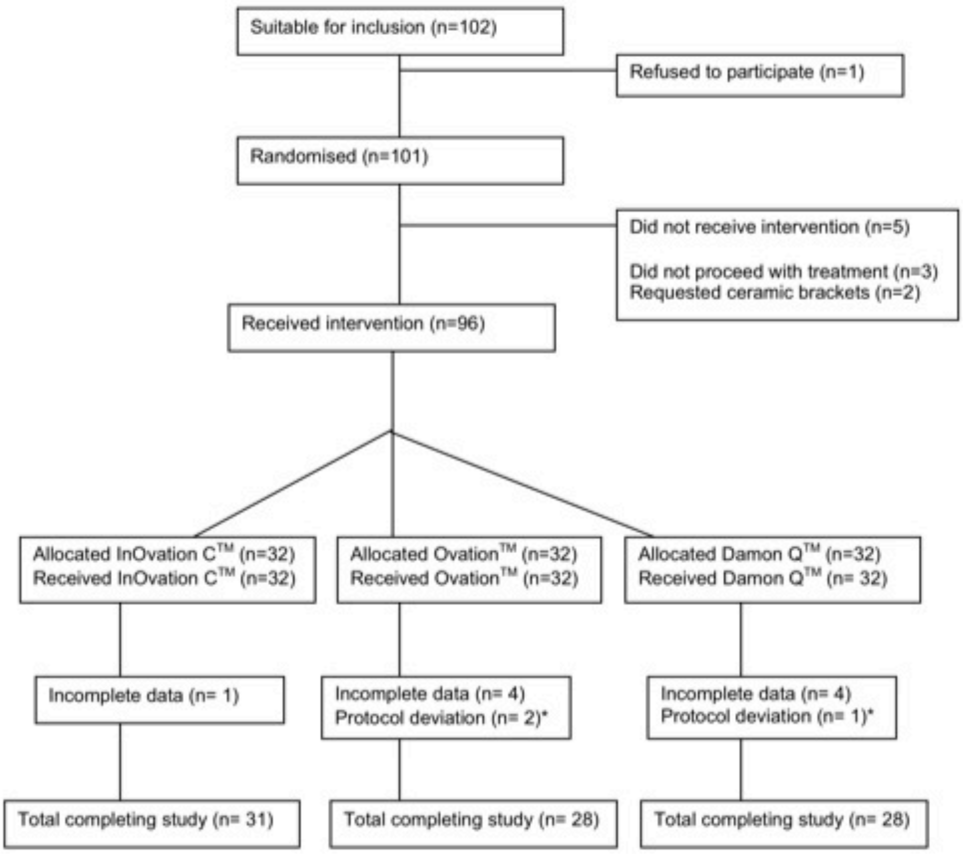


Figure 20. CONSORT diagram showing the flow of participants.

* 3 participants had both protocol deviations and incomplete data

7.16.2. Baseline characteristics of the sample

Little difference was found between the three groups in terms of demographic characteristics (Table 21). Overall there were slightly more male (n=49, 51%) than female subjects. The majority were white Caucasian (n=81, 84%). Participants had a wide range of malocclusions with a large proportion of Class III cases (n=42, 44%). Overall, there were 8 operators, although the great majority were treated by one operator (n=73, 76%). Subjects in the InOvation C^{TM} group were slightly older than those in the other groups, with the mean overall age being 19.7 years. The degree of crowding in all three groups was mild with a mean value of 2.47mm (SD 2.28).

Table 21. Demographic and clinical characteristics of the sample (n=96).

Variable		Damon Q™ n (%) or Mean (SD)	In-Ovation C™ n (%) or Mean (SD)	Ovation™ n (%) or Mean (SD)	Overall n (%) or Mean (SD)
Site	East Kent Hospitals	21 (66)	22 (69)	22 (69)	65 (68)
	The Royal London Dental Institute	11 (34)	10 (31)	8 (25)	29 (30)
	Southend NHS Foundation Trust	0 (0)	0(0)	2(6)	2 (2)
Gender	Male	14 (44)	14 (44)	21 (66)	49 (51)
	Female	18 (56)	18 (56)	11 (34)	47 (49)
Ethnicity	White Caucasian	26 (81)	27 (84)	28 (88)	81 (84)
	Asian Caucasian	5 (16)	3 (9)	2 (6)	10 (10)
	Afro-Caribbean	1 (3)	2 (2)	1 (3)	4 (4)
	Oriental	0 (0)	0 (0)	1 (3)	1 (4)
Operator	1	24 (75)	27 (84)	22 (69)	73 (76)
	2	2 (6)	3 (9)	2 (6)	7 (7)
	3	4 (13)	0 (0)	1 (3)	5 (5)
	4	2 (6)	0 (0)	2 (6)	4 (4)
	5	0 (0)	0 (0)	1 (3)	1 (1)
	6	0 (0)	2 (6)	1 (3)	3 (3)
	7	0 (0)	0 (0)	1 (3)	1 (1)
	8	0 (0)	0 (0)	2 (6)	2 (2)
Age		18.9 (2.9)	22.5 (8.5)	18.6 (3.4)	19.7 (5.9)
Malocclusion	Class I	9 (28)	5 (16)	6 (19)	20 (21)
	Class II division 1	7 (22)	8 (25)	8 (25)	23 (24)
	Class II division 2	1 (3)	9 (28)	1 (3)	11 (11)
	Class III	15 (47)	10 (31)	17 (53)	42 (44)
Crowding	mm	2.3 (2.64)	2.59 (1.99)	2.56 (2.22)	2.47 (2.28)
Maxillary incisor inclination	Degrees	112.5 (6.47)	109.25 (6.73)	111.25 (7.23)	111.24 (6.94)

Values are given as mean (SD)* or as frequency (%) ^

Table 22. Maxillary transverse dimensions and incisor inclination before and after alignment. Data are presented as Mean (SD).

Outcome		Damon Q™	InOvation C™	Ovation™
Pre-treatment maxillary transverse dimensions	Inter-canine	32.64 (3.07)	32.64 (2.89)	33.5 (2.64)
	Inter-first premolar	38.37 (3.45)	38.94 (3.61)	39.42 (4.01)
	Inter-second premolar	43.76 (3.66)	43.95 (3.55)	44.72 (3.73)
	Inter-molar	49.41 (3.62)	49.06 (4.26)	50.02 (3.5)
Post-treatment maxillary transverse dimensions	Inter-canine	34.62 (1.85)	34.42 (2.2)	34.38 (1.85)
	Inter-first premolar	42.88 (1.87)	42.7 (2.46)	43.18 (2.08)
	Inter-second premolar	47.61 (2.25)	47.73 (2.83)	48.31 (2.43)
	Inter-molar	50.68 (2.32)	50.87 (3.39)	51.48 (2.9)
Change in maxillary transverse dimensions	Inter-canine	1.97 (2.16)	1.78 (2.21)	0.88 (2.18)
	Inter-first premolar	4.51 (2.68)	3.75 (2.31)	3.7 (3.19)
	Inter-second premolar	3.96 (2.51)	3.78 (1.91)	3.59 (2.8)
	Inter-molar	1.22 (2.26)	1.82 (1.59)	1.41 (2.08)
Change in maxillary first molar inclination*	Degrees	-2.04 (5.90)	-1.38 (5.08)	-1.36 (5.66)
Pre-treatment maxillary incisor inclination	Degrees	113.28 (6.47)	109.25 (6.73)	111.25 (7.23)
Post-treatment maxillary incisor inclination	Degrees	114.83 (5.79)	112.49 (5.34)	114.26 (5.94)
Change in maxillary incisor inclination	Degrees	1.12 (3.88)	3.25 (6.89)	2.84 (5.68)

Differences based on pre- and post-treatment values from subjects completing the study

* Negative values indicate buccal movement of the crown relative to the root

Table 23. Coefficients and 95% Confidence Intervals (CIs) for effect of appliance type on outcome variables (transverse dimensions, incisor and molar inclination changes).

Outcome	Variable	Category	B (95% CIs)	P value
Inter-canine width	Appliance	Damon™	Reference	
		InOvation C™	-0.19 (-0.95, 0.57)	0.62
		Ovation™	-0.66 (-1.44, 0.12)	0.10
	Initial ICW	Per unit (mm)	0.45 (0.34, 0.56)	<0.01
	Crowding	Per unit (mm)	-0.02 (-0.16, 0.11)	0.73
Inter-first premolar width	Appliance	Damon™	Reference	
		InOvation C™	-0.19 (-1.27, 0.21)	0.16
		Ovation™	-0.29 (-1.05, 0.47)	0.45
	Initial IPMW1	Per unit (mm)	0.46 (0.37, 0.55)	<0.01
	Crowding	Per unit (mm)	0.27 (0.13, 0.41)	<0.01
Inter-second premolar width	Appliance	Damon™	Reference	
		InOvation C™	-0.16 (-0.88, 0.56)	0.66
		Ovation™	-0.05 (-0.79, 0.69)	0.89
	Initial IMPMW2	Per unit (degree)	0.62 (0.53, 0.70)	<0.01
	Crowding	Per unit (mm)	0.40 (0.26, 0.54)	<0.01
Inter-molar width	Appliance	Damon™	Reference	
		InOvation C™	0.40 (-0.31, 1.11)	0.27
		Ovation™	0.32 (-0.41, 1.05)	0.38
	Initial IMW	Per unit (mm)	0.68 (0.60, 0.75)	<0.01
	Crowding	Per unit (mm)	0.21 (0.08, 0.34)	<0.01
Maxillary incisor inclination	Appliance	Damon™	Reference	
		InOvation C™	-0.22 (-2.58, 2.14)	0.85
		Ovation™	0.44 (-1.93, 2.80)	0.71
	Initial inclination	Per unit (degree)	0.53 (0.38, 0.67)	<0.01
	Crowding	Per unit (mm)	0.47 (0.03,0.90)	<0.04
Maxillary molar inclination	Appliance	Damon	Reference	
		InOvation C	0.91 (-1.95, 3.78)	0.53
		Ovation	0.67 (-2.24, 3.58)	0.65
	Initial inclination	Per unit (degree)	-0.06 (-1.7, 0.05)	0.32

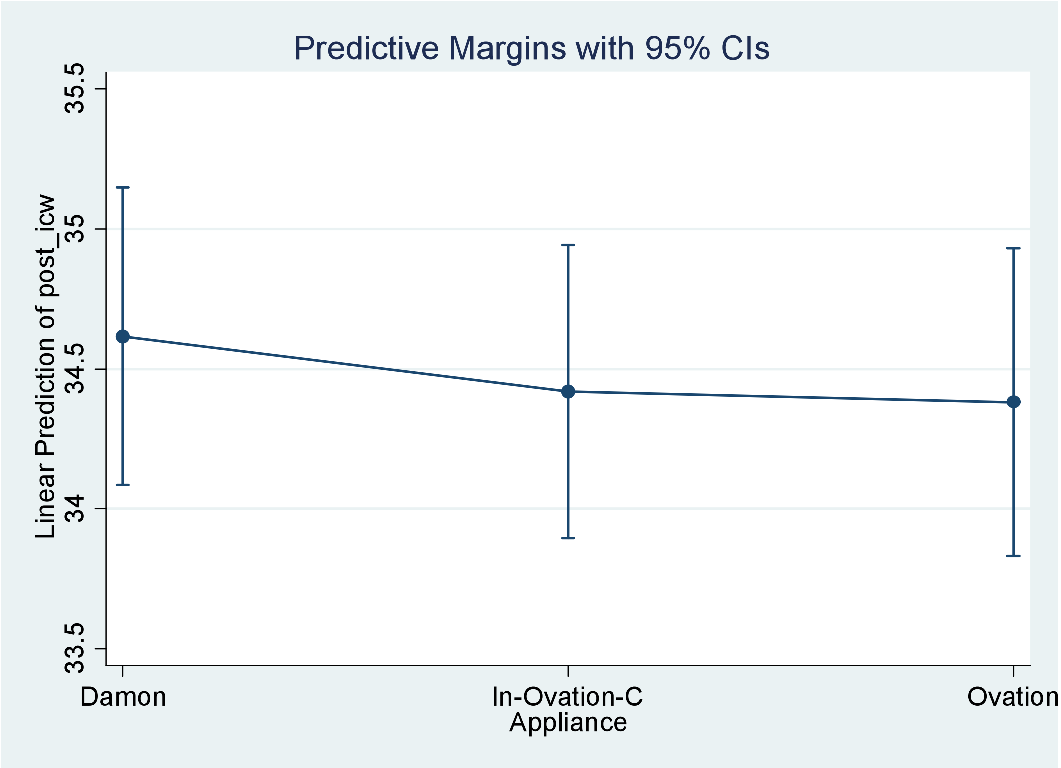


Figure 21. Predictive margins and associated 95% CIs for post-treatment maxillary inter-canine width based on appliance type.

7.16.3. Treatment changes

Inter-canine dimension

Inter-canine dimension increased in all three groups with slightly larger increases in the Damon Q™ group (Tables 22 and 23). A smaller increase in inter-canine width arose with both InOvation C™ (-0.19mm, 95%CI: -0.95, 0.57, $p=0.62$) and Ovation™ (-0.66mm, 95% CI: -1.44, 0.12, $p=0.10$) compared to Damon™ after adjusting for initial inter-canine width and pre-treatment crowding. Those differences did not reach statistical significance (Figure 21). In the adjusted analysis, initial inter-canine width was a significant predictor of the post-treatment value ($\beta=0.45$, 95% CI: 0.34, 0.56, $p< 0.01$), whereas a significant effect of pre-treatment crowding was not identified ($\beta= 0.02$, 95 CI%: -0.16, 0.11, $p=0.73$).

Inter-premolar dimensions

Similarly, inter-first premolar and inter-second premolar dimensions increased considerably in all three groups; however, no association was again found between appliance type and post-treatment inter-premolar width after adjusting for baseline differences in inter-premolar dimensions and crowding (Table 23, Figures 22 and 23). In the adjusted model, both crowding and pre-treatment inter-premolar dimensions were found to be significant predictors of the post-treatment values with the final inter-second premolar dimension increasing by 0.4mm for each millimeter of crowding (β=0.4, 95% CI: 0.26,0.54, p<0.01).

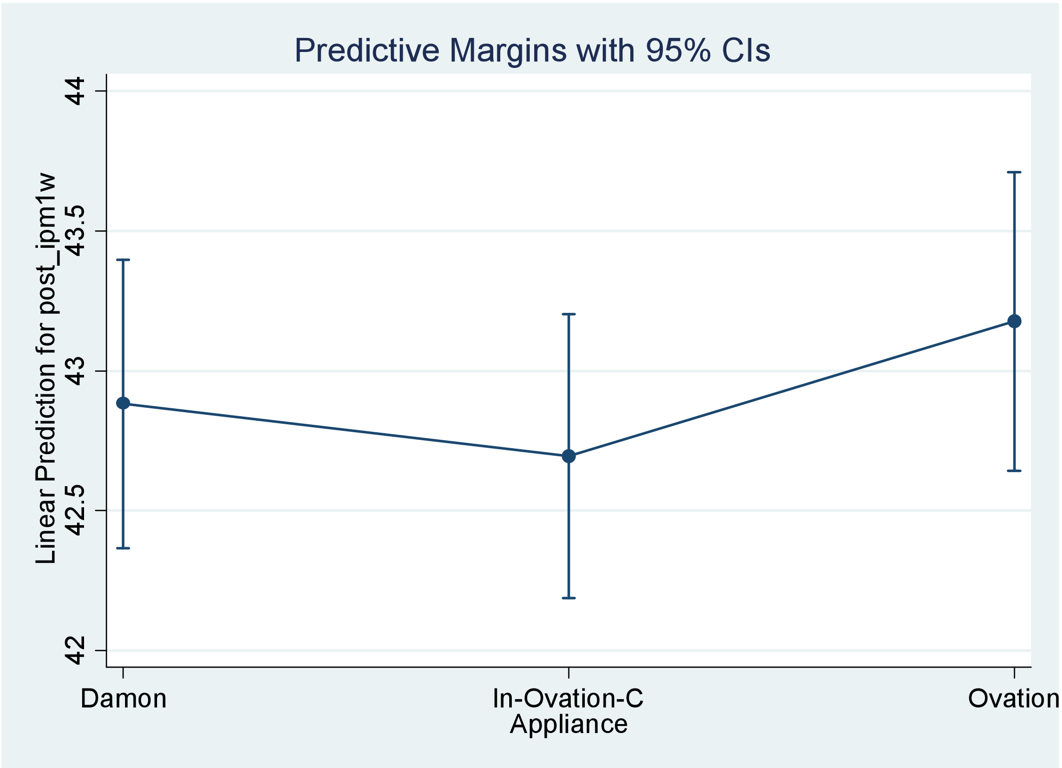


Figure 22. Predictive margins and associated 95% CIs for post-treatment maxillary inter-first premolar width based on the type of appliance.

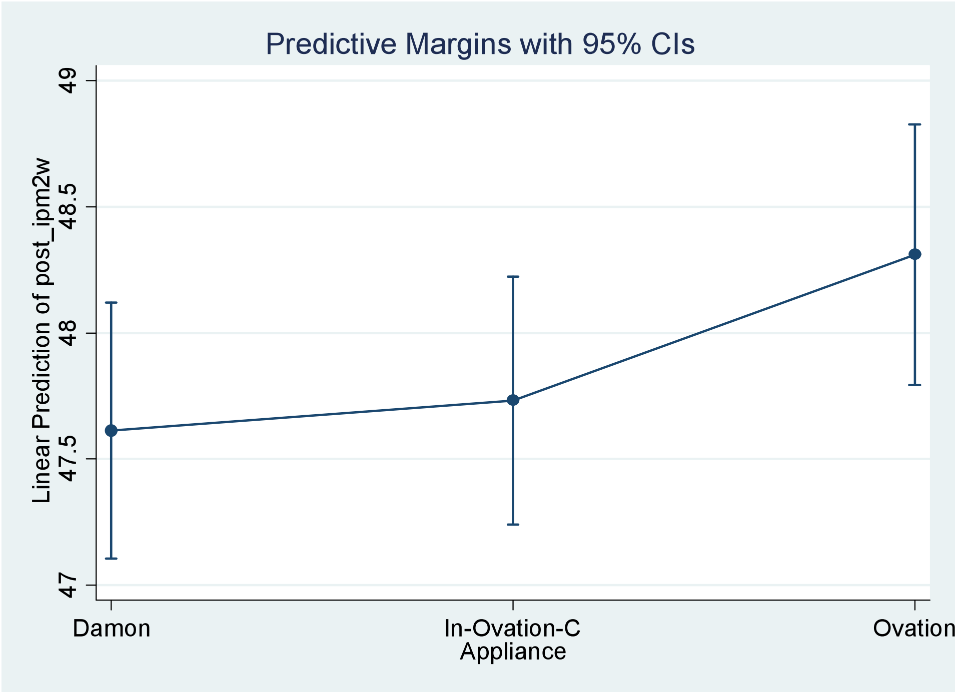


Figure 23. Predictive margins and associated 95% CIs for post-treatment maxillary inter-second premolar width based on the type of appliance.

Inter-molar dimension

Increases in inter-molar dimension occurred relatively uniformly in all three groups (Table 21, Figure 24); however, the magnitude of changes was less than that arising in the maxillary premolar dimensions. Mean increases of just 1.22mm arose in inter-molar width with Damon Q^{TM}. After accounting for pre-treatment values and crowding in the adjusted model (Table 22), no difference could be detected between inter-molar width developing with Damon Q^{TM} and InOvation C^{TM} (β=0.40, 95% CI: -0.31, 1.11, p= 0.27) or Damon Q^{TM} and the conventional system (β=0.32, 95% CI: -0.41, 1.05, p= 0.38). As with other transverse changes, both initial inter-molar width (β= 0.68, 95% CI: 0.60, 0.75 p<0.01) and crowding (β= 0.21, 95% CI: 0.08,0.34, p<0.01) were both found to have a significant influence on transverse changes in the adjusted model (Table 23).

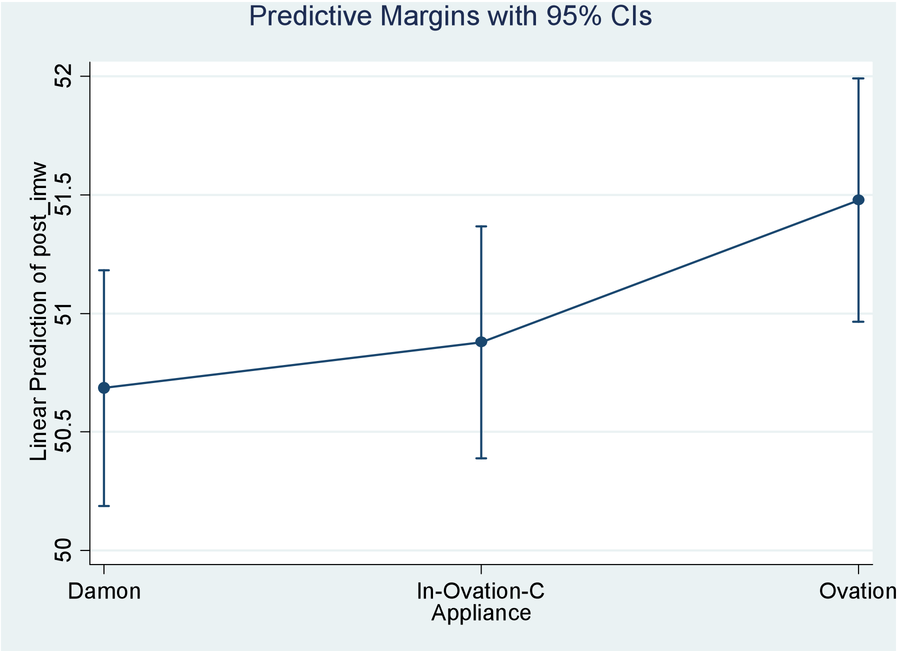


Figure 24. Predictive margins and associated 95% CIs for post-treatment maxillary inter-molar width based on the type of appliance.

First molar and central incisor inclination

In the unadjusted model the mean increase in maxillary incisor inclination ranged from 1.12 degrees (Damon Q^{TM}) to 3.25 degrees (InOvation C^{TM}). After accounting for pre-treatment values and crowding in the adjusted model, no statistical difference in incisor inclination could be found between either Damon Q^{TM} and InOvation C^{TM} (β= -0.22mm, 95%CI: -2.58, 2.14, p=0.85, Figure 25) or Damon Q^{TM} and Ovation^{TM} (β= 0.44mm, 95%CI: -1.93, 2.8, p=0.71). Pre-treatment maxillary incisor inclination (β= 0.53, 95% CI: 0.38, 0.67, p<0.01) and pre-treatment crowding (β= 0.47, 95% CI: 0.03, 0.90, p<0.04) were both significant predictors of post-treatment maxillary incisor values. Little change in molar inclination was observed in all three groups. Overall, a small degree of increased buccal crown inclination was found; the degree of buccal flaring was slightly greater in the Damon Q^{TM} group, with 0.66 degrees more change than with InOvation C^{TM} (Table 22). However, this difference was not found to be of statistical significance (0.91, 95% CI: -1.95, 3.78, p=0.53, Figure 26). Similarly, slightly more molar flaring was observed in the Damon Q^{TM} group than with Ovation^{TM}; however, the difference did not reach statistical significance (0.67, 95% CI: -2.24, 3.58, p=0.65).

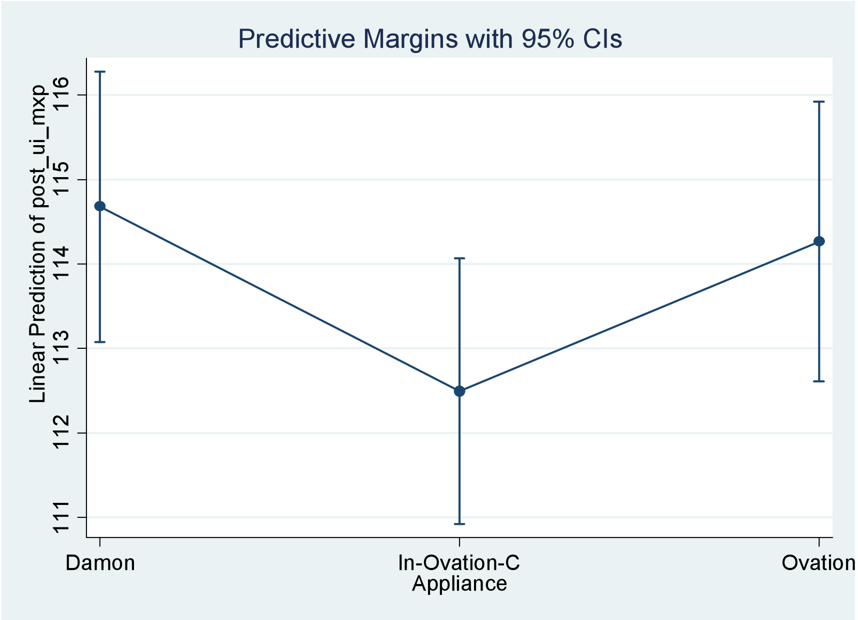


Figure 25. Predictive margins and associated 95% CIs for post-treatment maxillary incisor inclination based on the type of appliance.

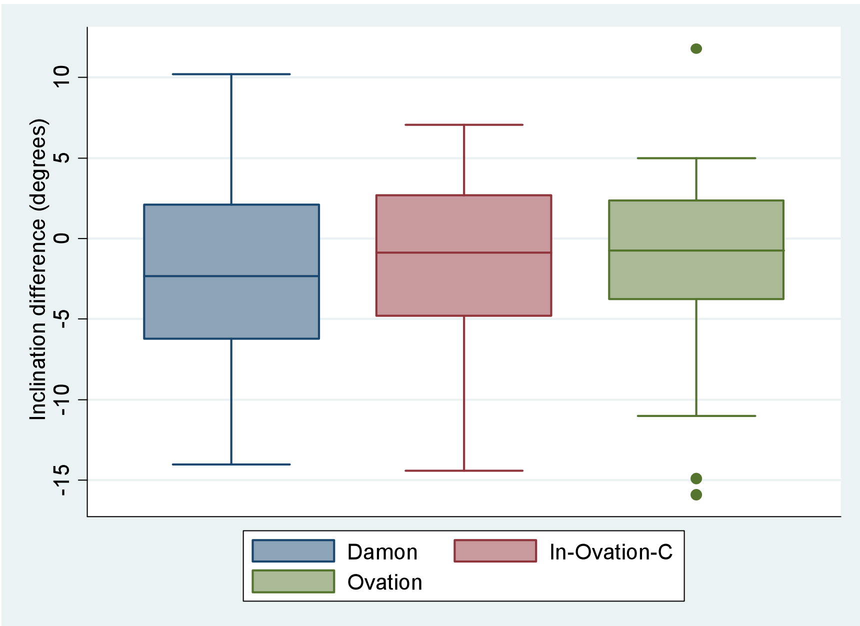


Figure 26. Box plots showing the median and range of values of molar inclination difference with each fixed appliance system.

Pairwise correlation demonstrated a positive correlation between pre-treatment inter-canine dimensions and increases in transverse dimensions posteriorly ($p < 0.001$; Table 24, Figure 27). The correlation coefficients between pre-treatment inter-canine dimension and inter-first premolar, inter-second premolar and inter-molar widths were 0.63, 0.67 and 0.65, respectively.

Table 24. Relationship between initial inter-canine dimension and changes in inter-premolar and inter-molar dimensions.

	Pre-treatment inter-canine width
Post-treatment inter-first premolar dimension	0.63*
Post-treatment inter-second premolar dimension	0.67*
Post-treatment inter-molar dimension	0.65*

* $p<0.001$

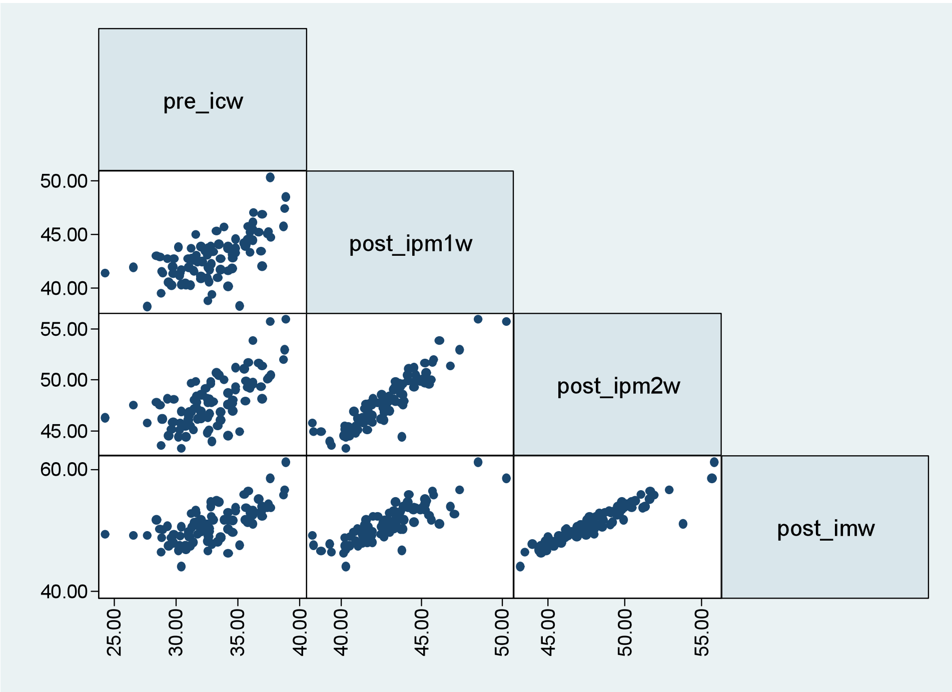


Figure 27. Correlation matrix between pre-treatment inter-canine dimension and maxillary inter-premolar and inter-molar dimensions.

7.17 Discussion

The widespread adoption of self-ligating brackets has courted controversy with advocates of self-ligation systems being optimistic about their potential merits overlooking the findings from clinical research studies. A significant driver for the popularity of SLBs has been the promise of relatively efficient and simple orthodontic treatment with a reduced dependence on extractions to facilitate orthodontic alignment. The principal aim of this RCT was to ascertain whether the pattern of orthodontic alignment attained with SLBs was distinct from that achieved with conventional fixed appliance systems. Similar studies have previously been undertaken (Pandis *et al.*, 2007; Scott *et al.*, 2008a; Fleming *et al.*, 2009a; Pandis *et al.*, 2010a; Cattaneo *et al.*, 2011) but none of these have incorporated both active and passive self-ligating systems and a control group focusing on non-extraction treatment. Just one recent study has involved comparison of arch dimensional and inclination changes with active and passive SLBs, although this study lacked a control group treated with conventional brackets (Cattaneo *et al.*, 2011).

The results of this prospective clinical trial support the null hypothesis that the use of a range of fixed appliances does not in itself have an influence on arch dimensional changes during orthodontic alignment. Arch dimensional changes with both passive and active self-ligation could not be differentiated from those arising with conventional systems. Similarly, while relative restraint of the maxillary incisors during alignment has been attributed to passive self-ligation, this concept was not borne out in this investigation with marginal advancement of the maxillary incisors arising with all three systems. This finding is in keeping with the majority of previous research, which predominantly failed to highlight a difference in alignment pattern with either conventional brackets or passive self-ligation in both extraction (Scott *et al.*, 2008a) and non-extraction cases (Pandis *et al.*, 2007; Fleming *et al.*, 2009a; Pandis *et al.*, 2010a). The only exceptions in previous reports were minor but statistically significant increases in inter-molar width changes with passive self-ligating systems (Pandis *et al.*, 2007; Fleming *et al.*, 2009a; Pandis *et al.*, 2010a). This finding was, however, not replicated in the present study.

The magnitude of expansion recorded in the present study was in keeping with previous prospective investigations (BeGole *et al.*, 1998; Franchi *et al.*, 2006). In particular, significant changes occurred in the premolar region with up to 4.51mm of expansion arising with Damon Q™ in the first premolar region. The changes are slightly greater than reported by Franchi *et al.* (2006) in a prospective follow-up of 20 patients treated with fixed appliances with low friction ligatures over the initial 6 months of appliance therapy. Franchi *et al.* (2006) found expansion of 1.71 to 3.65mm in maxillary transverse dimensions with increases peaking in the premolar region. Inter-molar expansion of 1.71mm was related to both bodily movement and tipping with 4.33 degrees of buccal flaring arising (Franchi *et al.*, 2006). Slightly larger changes were reported in an observational study by BeGole *et al.* (1998). The relatively large dimensional increases reported in the present study may relate to use of Damon™ archwires while Tru-arch™ medium form wires were used by Franchi *et al.* (2006). Damon™ wires have a broad arch shape, particularly in the buccal segments and may have contributed to the degree of expansion reported. To definitively prove this, however, would require further prospective research. Moreover, a recent randomised study by Cattaneo *et al.* (2011) with combined use of Damon™ wires and brackets but narrower wires with active self-ligating brackets reported similar levels of first premolar expansion with mean values of 4.5 and 4.3mm in the active and passive groups, respectively. Slightly greater inter-molar (0.9mm) and inter-second premolar expansion (0.7mm) were noted with the Damon™ system, however, suggesting that any effect of the broadened archwire may be exerted further posteriorly (Cattaneo *et al.*, 2011).

The magnitude of inter-molar expansion was relatively minor peaking at 1.82mm in the active self-ligation group; the inclination changes reported were correspondingly small with buccal flaring not exceeding 2.1 degrees in any of the groups. This degree of tipping is less than that reported by Franchi *et al.* (2006) and is likely to reflect progression into rectangular steel wires with greater torque control being exhibited, while the study by Franchi *et al.* (2006) did not involve wire advancement beyond round 0.016 inch NiTi wires. It would be intuitive to expect tipping movements to predominate during the initial stages before torque expression is introduced and enhanced with increasing rectangular wire gauge. Cattaneo *et al.* (2011) reported significant buccal flaring of premolars (11.7 to 13.5 degrees) in their investigation using CBCT scanning, although these changes occurred in conjunction with significant transverse changes. It is, therefore, likely that the inter-premolar changes reported in the present study were predominantly a product of buccal flaring rather than bodily movement and alveolar remodeling. It was initially also planned to assess the effects of transverse changes on the periodontium with a CBCT scan after the alignment phase. Recent research involving CBCT scans both prior to and following alignment alluded to a reduction in buccal bone volume in the maxillary first premolar region of 16.7 to 22.6% with InOvation R™ and Damon MX™, respectively. These changes occurred in conjunction with premolar expansion of the order of 4.3 to 4.5mm (Cattaneo *et al.*, 2011). It would therefore be intuitive to expect a similar diminution in buccal bone volume in the present study.

Relatively minor amounts of expansion were identified in the canine and molar region in the present study with the largest increments in the premolar region. This finding is in keeping with allied research involving conventional brackets, low friction elastomerics and self-ligating brackets (Franchi *et al.*, 2006; Cattaneo *et al.*, 2011). This pattern of preferential expansion in the premolar region may be attributed to arch form changes in tandem with relatively broad archwire forms in the premolar region. In addition, the root surface area of the premolars is less than that of the neighbouring canines and premolars, therefore presenting less anchorage to resist transverse changes. In addition, maxillary canines are often buccally-placed initially due to crowding; consequently, alignment of the canines is likely to be accompanied by either little change or a reduction in inter-canine width. This pattern was confirmed in the subset analysis (Table 24) with a positive correlation identified between pre-treatment inter-canine dimensions and increases in transverse dimensions posteriorly. In the present study, for every millimeter increase in initial inter-canine width corresponding increases in inter-first premolar, inter-second premolar and inter-molar widths of 0.63, 0.67 and 0.65mm, respectively were found. This finding coupled with the presence of pre-existing crowding may help to explain some of the dramatic transverse changes reported in isolated cases with self-ligating brackets (Damon, 2005).

A Damon™ wire sequence was used in conjunction with each bracket system in the present study. Similar approaches were adopted previously (Scott *et al.*, 2008); however, other authors have varied both bracket type and archwire sequences in analyses of both alignment efficiency and arch dimensional changes with conventional and self-ligating brackets (Pandis *et al.*, 2007; Cattaneo *et al.*, 2011). While the applicability of this treatment protocol could be contested, on the basis that Damon™ wires are rarely used with conventional brackets, it was felt that this approach would lead to the most robust comparison of the passive self-ligating bracket with alternatives. As such, the confounding effects of differences between archwire materials and form could be discounted. The conclusion can, therefore, be made that this study constitutes a detailed and unbiased assessment of the effects of ligation mode on arch dimensional changes.

The present study was confined to an adult population as it was felt that this approach would limit the effects of growth on arch dimensional changes and inclination changes. Carter and McNamara (1998) reported mean annual changes in 0.025mm from 17 to 48 years; similarly, little change in the inclination of the maxillary teeth can be expected after 16 years. Consequently, the requirement for an untreated control group was obviated; it was also felt that depriving adolescents of necessary treatment would be difficult to justify from an ethical perspective. The changes reported are therefore largely attributable to the appliances in isolation, minimising confounding effects of growth and maturation. Referral patterns and acceptance criteria dictated that many older patients seen in a hospital setting are accepted for treatment in preparation for combined orthodontic-surgical treatment; hence, a wide variation of malocclusions with a relatively high proportion of Class III malocclusions were encountered in the present research. Consequently, the results may be representative of a wide range of orthodontic discrepancies, although further research is required to confirm this.

There are undeniable merits associated with the use of self-ligating brackets (See Chapters 2 and 4). However, on the basis of this research, the practice of relying on appliances to generate unique arch form changes cannot be supported. The chief arbiters of treatment planning and extraction decisions rest with the trained clinician and should be predicated on the presenting malocclusion rather than the armamentarium at the clinician's disposal. Alignment of crowded arches may be mechanically simple and less cumbersome to achieve with self-ligating mechanisms; however, on the basis of the present research, relying on a bracket type to produce 'physiologically-mediated' arch form changes warranting non-extraction treatment appears unfounded.

7.18 Conclusions

In this randomised controlled trial no difference was observed in maxillary arch dimensions, or molar or incisor inclination after alignment with passive self-ligating brackets, active self-ligation or conventional brackets.

CHAPTER 8. OVERALL CONCLUSIONS.

Self-ligating brackets have become popular among orthodontic practitioners. However, as is the case with many established treatments in dentistry and orthodontics, the underlying evidence to prove many of the proposed benefits of SLBs is unconvincing. This research study was undertaken with the intention of analysing and improving this evidence base.

On the basis of the current data, the following conclusions can be made:

- There is insufficient evidence to support the use of self-ligating fixed orthodontic appliances over conventional appliance systems or *vice versa*. Self-ligating brackets do not confer particular advantage with regard to subjective pain experience. There is also no evidence of a difference in treatment effects on mandibular inter-canine or inter-molar width changes with SLBs. There is no evidence to suggest that orthodontic treatment is more or less efficient with self-ligating brackets. Moreover, meta-analysis of three randomised controlled trials indicates that overall treatment time may be slightly longer than with conventional systems.

- Digital models offer a high degree of validity compared to direct measurement on plaster models; differences between the approaches are likely to be within clinically acceptable limits.

- The validity of measurement of transverse dimensional changes on digital models was confirmed with respect to manual measurement using digital calipers. A novel technique for measuring inclination changes in the buccal segments was piloted and confirmed to have acceptable repeatability.

- In a three-parallel group, multicentre randomised controlled trial no difference in maxillary arch dimensions, or molar or incisor inclination could be found after alignment with passive self-ligating brackets, active self-ligation or conventional brackets.

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APPENDIX 1. Copies of published/accepted research papers based on this project.

Review Article

Self-Ligating Brackets in Orthodontics

A Systematic Review

Padhraig S. Fleming[a]; Ama Johal[b]

ABSTRACT

Objective: To evaluate the clinical differences in relation to the use of self-ligating brackets in orthodontics.

Materials and Methods: Electronic databases were searched; no restrictions relating to publication status or language of publication were applied. Randomized controlled trials (RCTs) and controlled clinical trials (CCTs) investigating the influence of bracket type on alignment efficiency, subjective pain experience, bond failure rate, arch dimensional changes, rate of orthodontic space closure, periodontal outcomes, and root resorption were selected. Both authors were involved in study selection, validity assessment, and data extraction. Disagreements were resolved by discussion.

Results: Six RCTs and 11 CCTs were identified. Meta-analysis of the influence of bracket type on subjective pain experience failed to demonstrate a significant advantage for either type of appliance. Statistical analysis of other outcomes was unfeasible because of inadequate methodological design and heterogenous designs.

Conclusions: At this stage there is insufficient high-quality evidence to support the use of self-ligating fixed orthodontic appliances over conventional appliance systems or vice versa. (*Angle Orthod.* 2010;80:575–584.)

KEY WORDS: Self-ligating; Orthodontic; Fixed appliance; Systematic; Meta-analysis

INTRODUCTION

Self-ligating brackets (SLBs) are not new conceptually, having been pioneered in the 1930s. They have undergone a revival over the past 30 years with a variety of new appliances being developed. A host of advantages over conventional appliance systems have been claimed typically relating to reduced frictional resistance.[1–4]

The most compelling potential advantages attributed to SLBs are a reduction in overall treatment time[5,6] and less associated subjective discomfort.[7] Other purported improvements include more efficient chairside manipulation[8] and promotion of periodontal health due to poorer biohostability. Preliminary retrospective research has pointed to a definite advantage, with a reduction in overall treatment time of 4 to 7 months and a similar decrease in required appointments.[5,6] Consequently, the use of SLBs has increased exponentially; over 42% of American practitioners surveyed reported using at least one system in 2008.[9] This figure was just 8.7% in 2002.[10]

Retrospective research may be confounded by a variety of factors including operator enthusiasm, different appointment intervals and archwire sequences, and multiple operators. However, prospective research relating to SLBs has emerged in recent years.

The purpose of this systematic review is to evaluate the clinically significant effects of SLBs on orthodontic treatment with respect to the quality of scientific evidence and the methodology of those reports. An understanding of clinical evidence on the impact of SLBs on orthodontic treatment would inform the orthodontist's decisions in relation to their choice of fixed appliance system.

MATERIALS AND METHODS

To be included in the review, trials had to meet the following selection criteria:

[a] PhD research student, Royal London Dental Institute, London, UK.

[b] Senior Lecturer/Honorary Consultant, Department of Orthodontics, Queen Mary's Institute of Dentistry, New Road, Whitechapel, London, UK.

Corresponding author: Mr Padhraig S. Fleming, Department of Orthodontics, Royal London Dental Institute, Whitechapel, London, London E1 1BB UK
(e-mail: padhraigfleming@hotmail.com)

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- Study design: Randomized and controlled clinical trials.
- Participants: Patients with full arch, fixed orthodontic appliance(s) treated with SLBs or conventional brackets (CBs).
- Interventions: Fixed appliance orthodontic treatment involving SLBs or CBs.
- Outcome measures: The outcome measures were alignment efficiency, pain experience, arch dimensional changes, rate of orthodontic space closure, bond failure rate, and periodontal effects related to both SLB and CB systems.

The efficiency of arch alignment, subjective pain experience, arch dimensional changes, rate of orthodontic space closure, and periodontal effects related to both appliances were recorded. Dichotomous data on the attachment failure rate related to each appliance were also noted.

Search Strategy for Identification of Studies

The following electronic databases were searched: MEDLINE via OVID (1950 to April 2009; see Appendix), EMBASE (1980 to April 2009), and Cochrane Central Register of Controlled Trials (The Cochrane Library, 2009). Language restrictions were not applied. Unpublished or "gray" literature was searched using ClinicalTrials.gov (www.clinicaltrials.gov) and the National Research Register (www.controlled-trials.com) using the term, "orthodontic and bracket." In addition, Pro-Quest Dissertation Abstracts and Thesis database was searched (www.lib.umi.com/dissertations) using "orthodontic*" and "ligat*." Conference proceedings and abstracts were also searched. Authors were contacted to identify unpublished or ongoing clinical trials and to clarify data as required. Reference lists of the included studies were screened for relevant research.

Assessment of Relevance, Validity, and Data Extraction

Assessment of research for inclusion in the review and assessment of validity and extraction of data were performed independently and in duplicate by two authors who were not blinded to the authors or the results of the research. Disagreements were resolved by discussion.

Six key methodological criteria were assessed: sample size calculation, random sequence generation, allocation concealment, reporting of withdrawals, blinding of measurement assessment, and the use of intention to treat analysis. An overall assessment of risk of bias (high, medium, low) was undertaken for each included trial using Cochrane Collaboration criteria. When five or more quality items were met, studies were considered to have a low risk of bias; three or more had medium risk; studies fulfilling less than three criteria were deemed to have high risk of bias. Only those at low to medium risk of bias were to be considered for meta-analysis.

Data Synthesis

A data extraction form was used to tabulate data on the outcomes of interest. Pain intensity using a visual analog scale (VAS) was obtained at all available time intervals. Pain scores assessed by means other than a zero-to-100 VAS were to be equated with this scale by multiplying the original scale employed by an appropriate factor.

Heterogeneity of the clinical studies was gauged by referring to each study assessing treatment protocol, timing of data collection, and measurement technique. Statistical heterogeneity was to be assessed by inspecting a graphical display of the estimated treatment effects from the trials along with their 95% confidence intervals. Chi-squared and I-squared tests for homogeneity were undertaken prior to each meta-analysis. Meta-analyses would also be possible only on studies reporting the same outcome measures at similar time intervals. Mean differences, standard deviations, and 95% confidence intervals were to be calculated for individual trials and combined using a random-effects model. Where necessary, sensitivity analyses were to be done with regard to the individual quality criteria, risk of bias, and publication status.

RESULTS

Description of Studies

Forty-three trials were initially deemed potentially relevant to the review, 42 being derived from MEDLINE via OVID and 1 study from the National Research Register[11] (www.controlled-trials.com). Following detailed assessment, 13 satisfied the inclusion criteria. One of these was subsequently omitted following retrieval of the full-text article; the remaining 30 studies were also excluded. However, after we contacted the authors of published trials, a further five studies were included. Of the 17 papers selected, 6 were randomized controlled trials (Table 1[11–27]).

Outcomes assessed include alleviation of irregularity using Little's irregularity index, subjective pain experience recorded using VASs, rate of orthodontic space closure, dimensional changes during orthodontic alignment, plaque retention, extent of root resorption developing during treatment, and attachment debond rate related to either appliance system.

Methodological Quality of Included Studies

The methodological quality of the trials considered in the review is presented in Table 2.[11–27] A priori sample-size calculations were undertaken in just six of the studies.[11,12,14,18,21,24] Generation of the random-number sequence was considered adequate in six trials using computer-generated random allocation.[11,12,14,17,18,24] In many of the studies, allocation was performed using a quasi-random method, with consecutive subjects being alternated between appliances. Six trials had acceptable allocation concealment.[11,12,14,17,18,24] Group allocation was not concealed in the split-mouth studies.[13,19,20]

Outcome assessment was blind in five studies.[12,14,20–22] There were no dropouts in six studies[16,19,21-23,27]; in studies with dropout, those lost to follow-up were reported on. However, statistical analysis was invariably per protocol with dropouts excluded from analysis. Overall, six studies were deemed to be at low risk of bias.[11,12,14,17,18,24]

Efficiency of Initial Orthodontic Alignment

Five trials considered the efficiency of initial orthodontic alignment.[12–16] One study used a three-dimensional measuring technique, making comparison unfeasible.[12] The remaining studies used two-dimensional measurement[13–16]; one of these trials incorporated a split-mouth design allowing consideration of just four mandibular contact points.[13] Alignment efficiency was assessed in the mandibular arch in all cases, with four studies confined to the lower anterior region and one study considering the arch from first molar to first molar.[12]

Miles et al,[13] Scott et al,[14] and Miles[15] followed similar treatment protocols with alignment efficiency assessed using Little's irregularity index in the mandibular arch recorded at similar intervals. Scott et al[14] assessed changes in the irregularity index 8 weeks after appliance placement; Miles[15] and Miles et al[13] both assessed residual irregularity 10 weeks and 20 weeks after placement of appliances. However, two of the studies[13,15] failed to include standard deviations and were at high risk of bias, precluding meta-analysis. Instead of measuring the amount of irregularity relieved in a given time frame, Pandis et al[16] calculated the time taken for alignment of the lower anteriors to occur.

Subjective Pain Experience

Four trials investigated subjective pain experience after initial placement of the appliances.[11,13,17,18] Of these, one split-mouth study considered pain reports after both the first and second visits, with patients indicating which system was associated with the greatest discomfort.[13] Data in three of the trials are presented as continuous pain scores from 0 to 100 on a 100-mm VAS.[11,17,18] One trial reported pain scores at 15 time intervals[11]; two trials used four time points: 4 hours, 24 hours, 3 days, and 7 days after appliance placement. The findings from these studies conflicted slightly with one study reporting a tendency to less pain experience with Damon 3 SLBs, although this finding did not reach statistical significance.[11] Reported pain peaked within 24 hours[11,17,18] before subsiding to near baseline levels 7 days after appliance placement. Three studies[11,17,18] were regarded as being at low risk of bias, and they reported similar outcomes permitting statistical comparison; pain scores at four analogous time intervals were extracted from each study to facilitate this.[11] Pain intensity over the first 7 days was reported in three studies involving 160 patients, with 83 in the SLB group and 77 in the CB group. Patients in the SLB group reported a mean difference in pain intensity of 0.99 to 5.66 points lower than in the CB group, the greatest difference being reported 3 days after appliance placement (Figures 1–4). However, differences were not of statistical significance.

Two studies[13,18] reported greater pain experience during chairside manipulation of self-ligating appliances. However, as the mechanisms of archwire engagement and disengagement are very different using SmartClip[18] and Damon 2,[13] it was felt that direct statistical comparison of this research finding would be invalid.

Bond Failure Rate

Two studies have considered failure of bonded attachments over 20 weeks[13] and 12 months.[19] The date used for assessing failure or time taken for failure to occur was not reported, and only first-time failures for each tooth were recorded. No significant differences were noted in the more extensive study.[19]

Plaque Retention and Periodontal Health

Two trials have compared the impact of SLBs and elastomeric ligation on plaque retention.[20,21] A split-mouth design was used in one study assaying plaque specimens harnessed 1 and 5 weeks after bonding.[20] Longer term effects of bracket system on periodontal health and accumulation of debris has also been assessed.[22]

Pellegrini et al[20] investigated the influence of method of archwire ligation on plaque retention using ATP-driven bioluminescence to assess bacterial load. Mean streptococcal and total bacterial levels harvested from tooth surfaces were lower with the SLB ($P < .05$). A further prospective trial, however, failed to show an association between bracket type and bacterial load.[21] This finding may reflect the different measurement technique employed involving estimation of salivary levels of *Streptococcus mutans*.[21]

Furthermore, Pandis et al[22] failed to demonstrate a link between bracket type and periodontal health following removal of orthodontic appliances. It appears that, while bracket type might influence bacterial load

Table 1. Summary of Included Research

Study	Methods	Participants	Interventions	Outcomes	Notes
Pringle et al (2009)[11]	RCT. Observed for 8 d after appliance placement	52 of 66 patients analyzed. Mean age: TruStraight, 16.1 (7.4) y; Damon 3, 15.2 (6.8). 24 male, 28 female	Group 1: 28 patients with TruStraight Group 2: 24 patients with Damon 3	Subjective pain experience at 2 time intervals on 8 consecutive d after appliance placement	
Fleming et al (2009)[12]	RCT. Observed at 8 wk	65 patients. Mean age, 16.28 (2.68) y. 22 male, 43 female	Group 1: 32 patients with SmartClip Group 2: 33 patients with Victory	Rate of initial alignment lower 6–6	Measurements were recorded in 3 dimensions
Miles et al (2006)[13]	CCT. Split-mouth design. Observed at 10 and 20 wk	58 consecutive patients. Mean age, 16.3 y. 18 male, 40 female	Lower appliance with Damon 2 or Victory brackets in alternate quadrants	Rate of initial alignment lower 3–3 Pain experienced at chairside and after appliance manipulation Bracket failure rate recorded	Contact point between central incisors omitted
Scott et al (2008)[14]	RCT. Observed at 8 wk and after mandibular alignment	62 patients recruited. Mean age, 16.27 (4.47) y. 32 male, 30 female	Group 1: 33 patients with Damon 3 Group 2: 29 patients with Synthesis	Rate of initial alignment lower 3–3 Time taken (days) to align lower arch in 0.019 × 0.025″ SSW[a] Root shortening of mandibular incisors	
Miles (2005)[15]	CCT. Observed at 10 and 20 wk	48 patients. Mean age, 17.1 y. 26 male, 32 female	Group 1: 24 patients with SmartClip Group 2: 24 patients with Victory	Rate of initial alignment lower 3–3	
Pandis et al (2007)[16]	CCT. Observed until alignment achieved	54 patients. Mean age, 13.7 (1.38) y. 11 male, 43 female	Group 1: 27 patients with Damon 2 Group 2: 27 patients with GAC Microarch	Time taken (days) to align lower 3–3	
Scott et al (2008)[17]	RCT. Observed for 1 wk after appliance placement	62 patients recruited. Mean age, 16.27 (4.47) y. 32 male, 30 female	Group 1: 33 patients with Damon 3 Group 2: 29 patients with Synthesis	Subjective pain experience at 4 h, 24 h, 3 d, and 7 d after appliance placement Analgesic consumption	
Fleming et al (2009)[18]	RCT. Observed for 1 wk after appliance placement and at chairside	48 of 66 patients analyzed. Mean age, 15.96 (2.56) y. 16 male, 32 female	Group 1: 26 patients with SmartClip Group 2: 22 patients with Victory	Subjective pain experience at 4 h, 24 h, 3 d, and 7 d after appliance placement Analgesic consumption Pain experience at chairside	
Pandis et al (2006)[19]	CCT. Split-mouth	62 patients. Mean age 14 y. 23 male, 39 female	Group 1: 43 patients with Damon 2 Group 2: 19 patients with GAC Microarch Appliances were bonded with Transbond Plus and Transbond XT (3M Unitek) or OrthoSolo and Enlight (ORMCO)	Bracket failure rate over a 12-mo period	First time failures only were recorded
Pellegrini et al (2009)[20]	CCT. Split-mouth. Observed 1 and 5 wk after appliance placement	18 patients. Mean age, 13.9 y. 5 male, 13 female	In-Ovation R or MiniOvation brackets on alternate lateral incisors	Mean bacterial counts and ATP-driven bioluminescence determinations	

Table 1. Continued

Study	Methods	Participants	Interventions	Outcomes	Notes
Pandis et al (2008)[21]	CCT. Observed 87 d after appliance placement	32 patients. Mean age, 13.6 (1.5) y. 16 male, 16 female	Group 1: 16 patients with Damon 2 Group 2: 16 patients with GAC Microarch	*S mutans* counts	
Pandis et al (2008)[22]	CCT. Periodontal examination before and after orthodontic treatment	100 patients. Age range, 12–17 y. 36 male, 64 female	Group 1: 50 patients with In-Ovation R Group 2: 50 patients with GAC Microarch	Plaque, gingival, and calculus indices, and probing depth for mesial, buccal, and distal aspects of mandibular 3–3	
Pandis et al (2006)[23]	CCT. Observed after orthodontic alignment	105 patients. Mean age, 16.14 (2.9) y. 36 male, 69 female	Group 1: 52 patients with Damon 2 Group 2: 53 patients with GAC Microarch	Change in inclination of U1 to SN and NA lines during treatment	
Fleming et al (2009)[24]	RCT. Observed at 30 wk after appliance placement	60 patients. Mean age, 16.35 (2.73) y. 21 male, 39 female	Group 1: 29 patients with SmartClip Group 2: 31 patients with Victory	Transverse dimensional change and incisor inclination change	
Pandis et al (2009)[25]	CCT. Observed after orthodontic treatment	54 patients. Mean age, 13.8 (1.5) y. 11 male, 43 female	Group 1: 27 patients with Damon 2 Group 2: 27 patients with GAC Microarch	Transverse dimensional change and incisor inclination change	
Miles (2007)[26]	CCT. Split-mouth. Observed at 5 weekly intervals during space closure	13 patients analyzed. Median age, 13.1 y. 5 male, 8 female	Clarity appliance placed upper 3-3 with SmartClip or Victory brackets on 2nd premolars	Rate of orthodontic space closure	
Pandis et al (2008)[27]	CCT. Observed after orthodontic treatment	96 patients. Mean age, 13.21 (1.64) y. 29 male, 67 female	Group 1: 48 patients with Damon 2 Group 2: 48 patients with GAC Microarch	Root length before and after treatment on panoramic radiographs	

[a] SSW indicates stainless steel wire.

Table 2. Methodological Assessment of Included Trials

Study	Design	Sample Size Calculation	Random Sequence Generation	Allocation Concealment	Reporting of Withdrawals	ITT	Blinding of Measurement	Risk of Bias
Pringle et al (2009)[11]	RCT[b]	Yes	Yes	Yes	Yes	No	No	Low
Fleming et al (2009)[12]	RCT	Yes	Yes	Yes	Yes	No	Yes	Low
Miles et al (2006)[13]	CCT[c]	No	Alternate	No	Yes	No	No	High
Scott et al (2008)[14]	RCT[d]	Yes	Yes	Yes	Yes	No	Yes	Low
Miles (2005)[15]	CCT	No	Alternate	No	Yes	No	No	High
Pandis et al (2007)[16]	CCT	No	Alternate	No	None	–	No	Medium
Scott et al (2008)[17]	RCT	n/a[a]	Yes	Yes	Yes	No	No	Low
Fleming et al (2009)[18]	RCT	Yes	Yes	Yes	Yes	No	No	Low
Pandis et al (2006)[19]	CCT	No	Alternate	No	None	–	No	Medium
Pellegrini et al (2009)[20*]	CCT	No	Unclear	Unclear	Yes	No	Yes	Medium
Pandis et al (2008)[21]	CCT	Yes	Alternate	No	None	–	Yes	Medium
Pandis et al (2008)[22]	CCT	No	Alternate	No	None	–	Yes	Medium
Pandis et al (2006)[23]	CCT	No	Alternate	No	None	–	No	Medium
Fleming et al (2009)[24]	RCT	Yes	Yes	Yes	Yes	No	No	Low
Pandis et al (2009)[25]	CCT	No	Alternate	No	Yes	No	No	High
Miles (2007)[26]	CCT	No	Alternate	No	Yes	No	No	High
Pandis et al (2008)[27]	CCT	No	Alternate	No	None	–	No	Medium

[a] Intention to treat analysis.
[b] RCT signifies randomized controlled trial.
[c] CCT signifies controlled clinical trial.
[d] Sample size was dictated by allied research on this population.[14]
* Author contacted to clarify randomization. No reply was received.

Study or Subgroup	SLB Mean	SLB SD	SLB Total	CB Mean	CB SD	CB Total	Weight	Mean Difference IV, Fixed, 95% CI
Fleming et al., 2009	46.81	24.41	26	46.43	24.07	22	31.3%	0.38 [-13.37, 14.13]
Pringle et al., 2009	33.71	25.2	24	43.71	30.11	28	26.2%	-10.00 [-25.03, 5.03]
Scott et al., 2007	63.67	23.18	33	60.11	23.3	27	42.4%	3.56 [-8.26, 15.38]
Total (95% CI)			**83**			**77**	**100.0%**	**-0.99 [-8.69, 6.71]**

Heterogeneity: Chi² = 1.99, df = 2 (P = 0.37); I² = 0%
Test for overall effect: Z = 0.25 (P = 0.80)

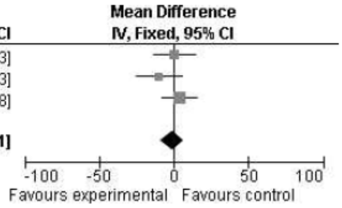

Figure 1. Meta-analysis and forest plot of pain scores (VAS) 4 hours after appliance placement in experimental (SLB) and control (CB) groups. VAS indicates visual analog scale; SLB indicates self-ligating bracket; CB indicates conventional bracket.

with appliances in situ, this effect may not be sustained after treatment.

Torque Expression and Arch Dimensional Change

In relation to the mandibular arch, Pandis et al,[16] Fleming et al,[24] and Pandis et al[25] reported identical incisor proclination and intercanine expansion with both appliance systems during arch alignment. Statistically greater intermolar expansion with self-ligating appliances has been shown in the latter studies.[24,25] Similar findings were not observed by Scott et al,[14] although this study involved assessment after mandibular premolar extraction, precluding direct comparison. There were insufficient trials of low- or medium-bias risk in homogenous groups to allow meta-analysis of this outcome.

Orthodontic Space Closure

Only one study considered the rate of orthodontic space closure[26] at intervals of 5 weeks until complete space closure was achieved. This study had an inadequate sample size, with 4 of 18 subjects (22%) failing to complete the study. Posted archwires were used on both sides; therefore, tooth movement on one side may not have been independent of the other.

Apical Root Resorption

Pandis et al,[27] using panoramic radiographs, reported no mean difference in the amount of apical root resorption of the maxillary incisors with Microarch and Damon 2 systems. Similar results were obtained by Scott et al,[14] who assessed changes in root lengths of mandibular incisors on periapical radiographs following arch alignment. The mean amount of resorption was slightly greater with the Damon 3 appliance (2.26 vs 1.21 mm), although the difference failed to reach statistical significance.

DISCUSSION

Most of the studies included were considered to be at low to medium risk of bias. However, a priori sample size calculations were reported in only six studies, increasing the risk of false negative outcomes. The method of randomization and allocation concealment was often inadequate or incompletely reported. Many studies used alternate allocation, which precluded concealment of the participant to group allocation. Seven studies reported no dropouts; in the remaining studies, dropouts were clearly outlined. A CONSORT flow diagram was included in just four studies.[11,14,17,25]

Per-protocol analysis was used in all studies, with dropouts being excluded from statistical analysis. Intention-to-treat analysis would be a more appropriate technique ensuring consideration of all subjects initially randomized, maintaining the benefits of randomization throughout the trial. Further prospective research in this area should be reported in accordance with the CONSORT guidelines[28]; this will improve the quality of research studies, permitting further meta-analyses, and will make components of research including method of randomization and allocation concealment more transparent.

Meta-analysis of the influence of bracket type on pain experience confirmed that SLBs do not have a clinically significant bearing on subjective pain experience. The

Study or Subgroup	SLB Mean	SLB SD	SLB Total	CB Mean	CB SD	CB Total	Weight	Mean Difference IV, Fixed, 95% CI
Fleming et al., 2009	61.46	25.35	26	67.7	17.83	22	34.5%	-6.24 [-18.51, 6.03]
Pringle et al., 2009	24.58	22.8	24	35.21	28.4	28	26.7%	-10.63 [-24.55, 3.29]
Scott et al., 2008	58.3	20.74	33	57.44	24.24	27	38.8%	0.86 [-10.70, 12.42]
Total (95% CI)			**83**			**77**	**100.0%**	**-4.66 [-11.86, 2.54]**

Heterogeneity: Chi² = 1.65, df = 2 (P = 0.44); I² = 0%
Test for overall effect: Z = 1.27 (P = 0.20)

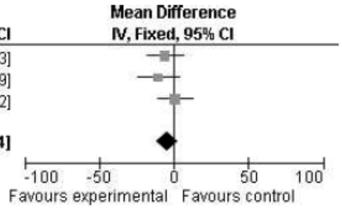

Figure 2. Meta-analysis and forest plot of pain scores (VAS) 24 hours after appliance placement in experimental (SLB) and control (CB) groups.

	SLB			CB				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Fleming et al., 2009	42.58	23.87	26	46.45	24.15	22	22.4%	-3.87 [-17.51, 9.77]
Pringle et al., 2009	5.67	7	24	17.29	23	28	51.8%	-11.62 [-20.59, -2.65]
Scott et al., 2007	42.94	23.08	33	38.19	26.43	27	25.8%	4.75 [-7.95, 17.45]
Total (95% CI)			**83**			**77**	**100.0%**	**-5.66 [-12.11, 0.79]**

Heterogeneity: Chi² = 4.34, df = 2 (P = 0.11); I² = 54%
Test for overall effect: Z = 1.72 (P = 0.09)

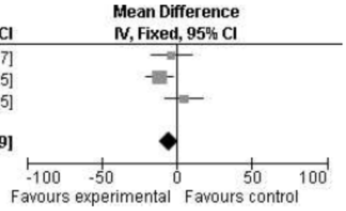

Figure 3. Meta-analysis and forest plot of pain scores (VAS) 72 hours after appliance placement in experimental (SLB) and control (CB) groups.

three studies included in the meta-analysis had discordant findings; one favored SLBs[11] and the other two studies demonstrated little difference between appliance systems. We can only speculate as to why this discrepancy arose; all studies were of high methodological quality and were carried out in similar settings, with analogous age and gender distribution.[11,17,18] The failure to highlight a significant bracket-related effect is compatible with previous research, which has failed to demonstrate a link between archwire material[29] or dimension[30] and pain experience. Clearly, pain is influenced by a variety of factors, with individual susceptibility being critical. Consequently, to definitively address this question, a well-designed, prospective study of a large sample is required.

Prospective research considering surrogate measures of treatment efficiency, including the efficiency of orthodontic alignment and rate of space closure, has shown little difference between fixed appliance types, with remarkable consistency. These findings are incompatible with retrospective research findings[5,6] and with manufacturers' claims of superior clinical performance. However, statistical comparison of these studies was not performed in view of differences in measuring alignment, methodological inadequacies related to some of the research, and incomplete reporting of results.

Arch dimensional changes arising with SLBs and conventional systems appear to be similar: identical levels of incisor proclination and intercanine expansion developed in both systems.[16,23–25] This outcome is at odds with claims that low-friction systems respond differently under soft tissue pressures. Nevertheless, two studies have suggested that greater mandibular intermolar expansion develops during alignment with SLBs.[24,25]

The finding of lower bacterial and streptococcal loads surrounding SLBs compared with conventional brackets during the initial stages of orthodontic treatment is of interest.[20] Longer term follow-up has highlighted the capacity of periodontal tissues to recover from this initial insult following appliance removal.[22] Nevertheless, it is unclear whether increased plaque accumulation has other detrimental effects, particularly decalcification. Further research is required to investigate this relationship further.

While evidence regarding the clinical application of SLBs is beginning to accumulate, the influence of bracket type on oral health-related quality of life is uninvestigated. There has also been no direct prospective comparison of overall treatment duration with conventional brackets and SLBs. Further research should be reported in accordance with the CONSORT guidelines[28] and should have adequate sample size to avoid Type II error.

CONCLUSIONS

- There is insufficient evidence to support the use of self-ligating fixed orthodontic appliances over conventional appliance systems or vice versa.
- SLBs do not confer particular advantage with regard to subjective pain experience.
- There is insufficient evidence suggesting that orthodontic treatment is more or less efficient with SLBs.

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	SLB			CB				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Fleming et al., 2009	17.08	16.47	26	18.52	18.31	22	15.6%	-1.44 [-11.37, 8.49]
Pringle et al., 2009	0.71	1.84	24	5.93	12.88	28	65.9%	-5.22 [-10.05, -0.39]
Scott et al., 2008	15.12	14.32	33	15.11	20.32	27	18.6%	0.01 [-9.08, 9.10]
Total (95% CI)			**83**			**77**	**100.0%**	**-3.66 [-7.58, 0.26]**

Heterogeneity: Chi² = 1.22, df = 2 (P = 0.54); I² = 0%
Test for overall effect: Z = 1.83 (P = 0.07)

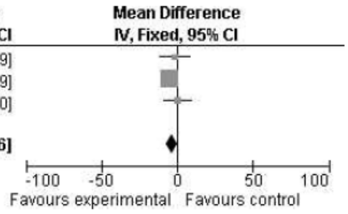

Figure 4. Meta-analysis and forest plot of pain scores (VAS) 7 days after appliance placement in experimental (SLB) and control (CB) groups.

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ORTHODONTICS & CRANIOFACIAL RESEARCH

REVIEW ARTICLE

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PS Fleming
V Marinho
A Johal

Orthodontic measurements on digital study models compared with plaster models: a systematic review

Authors' affiliation:
P.S. Fleming, V. Marinho, A. Johal, Queen Mary University of London, Barts and The London School of Medicine and Dentistry, Institute of Dentistry, London, UK

Correspondence to:
Dr Padhraig Fleming
PhD research student
Queen Mary University of London
Barts and The London School of Medicine and Dentistry
Institute of Dentistry
London E1 2AD
UK
E-mail: padhraigfleming@hotmail.com

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Abstract

Authors – Fleming PS, Marinho V, Johal A

The aim of this study is to evaluate the validity of the use of digital models to assess tooth size, arch length, irregularity index, arch width and crowding versus measurements generated on hand-held plaster models with digital callipers in patients with and without malocclusion. Studies comparing linear and angular measurements obtained on digital and standard plaster models were identified by searching multiple databases including MEDLINE, LILACS, BBO, ClinicalTrials.gov, the National Research Register and Pro-Quest Dissertation Abstracts and Thesis database, without restrictions relating to publication status or language of publication. Two authors were involved in study selection, quality assessment and the extraction of data. Items from the Quality Assessment of Studies of Diagnostic Accuracy included in Systematic Reviews checklist were used to assess the methodological quality of included studies. No meta-analysis was conducted. Comparisons between measurements of digital and plaster models made directly within studies were reported, and the difference between the (repeated) measurement means for digital and plaster models were considered as estimates. Seventeen relevant studies were included. Where reported, overall, the absolute mean differences between direct and indirect measurements on plaster and digital models were minor and clinically insignificant. Orthodontic measurements with digital models were comparable to those derived from plaster models. The use of digital models as an alternative to conventional measurement on plaster models may be recommended, although the evidence identified in this review is of variable quality.

Key words: dental models; digital model; plaster model; reproducibility; validity

Introduction

Three-dimensional imaging and modelling have undergone significant advances in recent years, raising the possibility of the development of the 'virtual orthodontic patient', where bone, soft tissue and teeth can be recreated in three dimensions (1). The panacea of complete three-dimensional digital conversion has been prompted in particular by the advent of cone beam computerized tomography and the refinement of three-dimensional facial imaging. A further cog in this process is the advent of digital study model scanning (2).

Digital study models were introduced commercially in 1999 by OrthoCad™ (Cadent, Carlstadt, NJ, USA) and in 2001 (emodels™; GeoDigm, Chanhassen, MN, USA). The technology used to generate digital study models varies considerably. Emodels scans the surface of a complete plaster model, whereas OrthoCad uses 'destructive scanning' with multiple scans of a model in thin slices. Emodels has software to 'slice through' the image, whereas OrthoCad actually slices through the model and images it. Direct scanning of impressions to generate digital models is also possible (Digimodel™; Orthoproof, Albuquerque, NM, USA), obviating the requirement for plaster models.

Study models for orthodontic diagnosis and treatment planning have traditionally been held in the form of physical plaster models, which are subject to loss, fracture and degradation. Digital storage eliminates inherent problems related to physical storage of models with up to 17 m^3 of storage space required for storage of traditional models for one thousand patients (3). The replacement of plaster orthodontic models with virtual information has further potential benefits including:

(1) instant accessibility of 3D information without need for the retrieval of plaster models from a storage area;
(2) the ability to perform accurate and simple diagnostic set-ups of various extraction patterns;
(3) virtual images may be transferred anywhere in the world for instant referral or consultation; and
(4) objective model grading analysis, for example, for Peer Assessment Rating (PAR) or American Board of Orthodontics (ABO) scoring.

The potential advantages of digital models for the quantification of orthodontic problems would be negated if the validity, efficiency and ease of linear and angular measurement of occlusal features with digital models were not comparable to those related to plaster models, the current 'gold standard' used routinely in clinical practice. This review aims at assessing the validity (4) of digital models by assessing agreement with measurements on hand-held plaster models.

Materials and methods

To be included in the review, trials had to meet the following inclusion criteria:

- Study design: Primary diagnostic study reporting consecutive, randomly selected or non-randomly selected subjects.
- Population: Treated and untreated orthodontic patients with or without malocclusion. Restrictions were not applied owing to age, gender or setting, but alginate impressions were to be poured within 24 h.
- Index test: Measurements on digital models (any).
- Reference standard/comparator: Measurements on unmarked plaster models (with dial or digital callipers).
- Outcome measures of interest included the validity of recordings of tooth size; transverse dimensions; irregularity index; arch width; crowding; Bolton ratio; occlusal indices; and inter-arch occlusal features. Time taken to measure hand-held plaster and digital models was also assessed.

Search strategy for the identification of studies

Relevant literature was identified by searching the following electronic databases: MEDLINE via OVID (1950 to January 2010), LILACS and BBO (1982 to January 2010). Language restrictions were not applied. Unpublished literature was to be identified through searches of ClinicalTrials.gov (http://www.clinicaltrials.gov), the National Research Register (http://www.controlled-trials.com) and Pro-Quest Dissertation Abstracts and Thesis database (http://www.lib.umi.com./dissertations). Search strategies are described in Table 1 according to the sources searched. Conference proceedings and abstracts were also searched. Authors were to be contacted to identify unpublished or ongoing research and to clarify findings as required. Reference lists of the included studies were also screened for potentially relevant research.

Assessment of relevance, methodological quality and data extraction

Assessment of research for inclusion in the review, quality assessment and extraction of data were performed independently by two investigators (PSF and AJ). Disagreements were resolved by joint discussion, and a third investigator (VM) was consulted where necessary.

Table 1. **Database search and study selection**

Database	Keywords	Results	Full articles retrieved	Articles selected
MEDLINE via OVID (1950 to January 2010	((digital$ or virtual or electronic or computer$ or software) and (model$ or cast$)) or emodel or orthocad) and ((plaster$ or stone or gypsum) and (model$ or cast$)) and (dental or orthod$ or tooth))	248	24	14
LILACS (1982 to 2010)	((digital$ or virtual or electronic$ or comput$ or software) and (model$ or cast$)) or emodel or orthocad) and ((plaster$ or gesso$ or stone or gypsum) and (model$ or cast$)) and (dent$ or orthod$ or tooth))	44	1	1
BBO	As LILACS above	55	0	0
ClinicalTrials.gov	Orthodontic and digital and plaster model	0	0	0
National Research Register	Orthodontic and digital and plaster model	0	0	0
Pro-Quest Dissertation Abstracts and Thesis database	'Orthodontic*', 'model*' and 'digital*'	0	0	0

Potentially relevant abstracts were selected, and full-text articles were retrieved for further screening. Researchers were not blinded to the authors or the results of the research. Data extracted on the characteristics of included studies broadly covered the following aspects: setting; participants; study design; reference standard(s); index/comparator test(s); number of examiners; and number of times the test was performed. Methodological quality was assessed by critically examining the methodology of the investigations. The Quality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist was followed, although not all items were strictly applicable as this review was not directly addressing diagnostic test accuracy.

Data synthesis

Heterogeneity between studies was gauged by referring to assessment measurement protocol/measurement technique; number of operators; and the outcome measure reporting the comparisons between the index and reference tests. Results were tabulated according to outcomes showing the estimates of the various measurements. The differences between the means of measurements on plaster and digital models were extracted. The narrative focus was on reporting the pattern of results by outcomes across all the included studies. Inferential statistical methods were not used for the estimation of summary measures, testing of differences between models/tests and investigations into heterogeneity. No tests or investigations were undertaken to detect reporting biases.

Results

Description of included studies

Forty abstracts were considered potentially relevant. Following screening, 29 full-text articles were retrieved. Of these, 12 failed to meet the inclusion criteria. A hand search of the references in the 14 articles satisfying the inclusion criteria identified three additional articles. Therefore, 17 articles were included in the review (Fig. 1 5–21). Reasons for exclusion at the final selection stage are outlined in Appendix 1.

The characteristics of the individual studies are given in Table 2. All investigations were based in dental university settings, typically in the permanent dentition. Subjects in the majority of studies had malocclusion and had no history of orthodontic treatment. Gender and ethnicity were unspecified in all studies. Subjects were aged 12–18 in one study (20), but age was

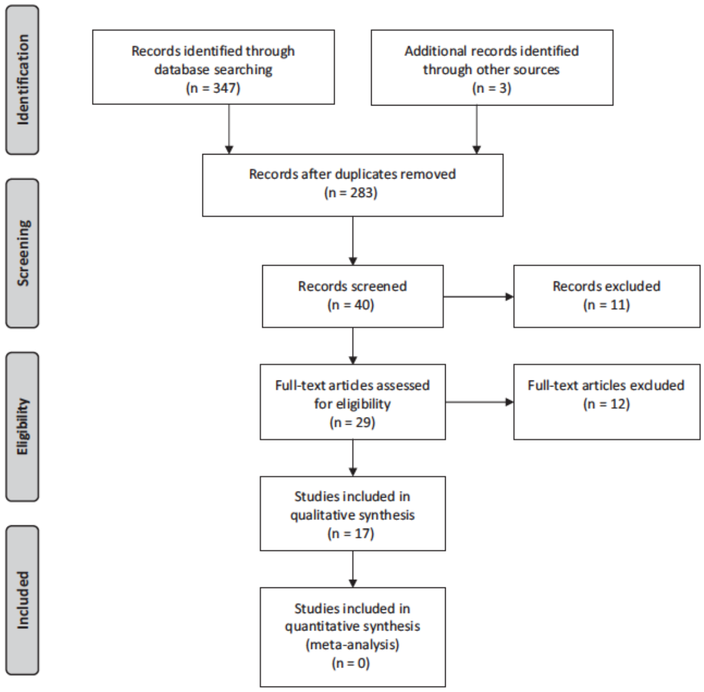

Fig. 1. Flow diagram of article retrieval.

unclear in the remainder. Clear information on study design was lacking in the majority of reports.

Seven digital model systems were assessed in these trials: OrthoCad; emodel; C3D-builder; ConoProbe; Easy3D Scan; Digimodels; and Cecile 3. Agreement between recordings on OrthoCad and plaster models was assessed in nine studies (5, 6, 8–10, 13, 15, 16, 19), between emodels and plaster models in three investigations (11, 12, 21) and using the other software systems in a single study each. Similar types of plaster models (index/comparator test) were used in each study. All digital recordings were compared to those derived from the direct measurement on plaster models using digital callipers. Either one or two (6, 8, 9, 11) sets of impressions were taken to produce digital and plaster models.

Significant variation was observed in the number of examiners carrying out the measurements and the number of times the readings were repeated. Ten examiners performed measurements in one trial (8). Measurements were taken three times by the researchers in four studies (5, 11, 14, 21) and eight times in one study (7).

Methodological quality of included studies

Where possible, the QUADAS tool (22) was adhered to. Therefore, methodological quality was assessed by critically examining the investigations in relation to the following: inclusion of a representative spectrum of patients (population recruitment and characteristics); use of appropriate reference standards; adequate description of index tests and reference standards; independent interpretation of the tests; independent interpretation of index and reference tests; and reporting of uninterpretable or intermediate data (Table 3).

Regarding the inclusion of a representative spectrum of patients, subjects were recruited either randomly or consecutively in most studies although the recruitment process and the characteristics of those recruited were not clearly outlined in seven studies (5, 7, 10, 12–14, 16,

Table 2. **Characteristics of included studies**

Study	Setting	Characteristics of participants	Study design	Index test/Reference standard	Examiners (readings per examiner)	Outcome measures
Tomassetti et al. (5)	University Orthodontic Department	22 subjects; USA, 11 pre- and 11 post-treatment; not more than 3 mm crowding.	Prospective	OrthoCad/Digital callipers	1 (3)	Bolton ratio; Time taken
Santoro et al. (6)	University Orthodontic Department	20 subjects; USA, permanent dentition; no missing teeth; stable occlusion with 3 occlusal contacts or more.	Prospective, enrolled randomly	OrthoCad/Digital callipers	2 (1)	Tooth size; Overjet; Overbite
Bell et al. (7)	University Orthodontic Department	22 subjects; UK	Prospective	C3D-builder (Uni. of Glasgow)/Digital callipers	1 (8)	Transverse and sagittal linear measurements
Quimby et al. (8)	University Orthodontic Department	50 subjects; USA, permanent dentition	Prospective, enrolled consecutively	OrthoCad/Digital callipers	10 (2)	Tooth size; Arch length; Transverse dimensions; Overjet; Overbite; Space available; Space required
Mayers et al. (9)	University Orthodontic Department	48 subjects; USA, permanent dentition	Prospective, enrolled consecutively	OrthoCad/Digital callipers	1 (2)	PAR score
Costalos et al. (10)	University Orthodontic Department	48 subjects; USA, permanent dentition; post-treatment; no edentulous space; no malocclusion.	Prospective	OrthoCad/Digital callipers	2 (1)	ABO score

Table 2. **Continued.**

Study	Setting	Characteristics of participants	Study design	Index test/Reference standard	Examiners (readings per examiner)	Outcome measures
Stevens et al. (11)	University Orthodontic Department	24 subjects; Canada, complete permanent dentition (from 1st molar to 1st molar) without previous orthodontics, pre-treatment models	Prospective, randomly selected from 225 records; three selected within each of 8 categories of malocclusion	Emodels/Digital callipers	3 (3 and 1)	PAR; Bolton ratio
Mullen et al. (12)	University Orthodontic Department	30 subjects; USA, Pre-treatment; complete permanent dentition (from 1st molar to 1st molar).	Prospective	Emodels/Digital callipers	1 (1)	Bolton ratio; Time taken
Okunami et al. (13)	University Orthodontic Department	30 subjects; USA, permanent dentition; post-treatment; no malocclusion.	Prospective	OrthoCad/Digital callipers	1 (1)	ABO score
Redlich et al. (14)	University Orthodontic Department	30 subjects; Israel, mixed and permanent dentition; 10 subjects each with mild, moderate and severe crowding.	Prospective	ConoProbe/Digital callipers	1 (3)	Tooth width; Arch l ength; Crowding
Hildebrand et al. (15)	University Orthodontic Department	36 subjects; USA, treated cases; consenting patients; no malocclusion.	Prospective, enrolled randomly	OrthoCad/Digital callipers	1 (1)	ABO score
Goonewardene et al. (16)	University Orthodontic Department	50 subjects; Australia, permanent dentition erupted including third molars.	Prospective	OrthoCad/Digital callipers	1 (1)	Tooth width; Arch length; Crowding Irregularity

Table 2. **Continued.**

Study	Setting	Characteristics of participants	Study design	Index test/Reference standard	Examiners (readings per examiner)	Outcome measures
Keating et al. (17)	University Orthodontic Department	30 subjects; UK	Prospective, enrolled randomly	Easy3D Scan/Digital callipers	1 (2)	Linear dimensions (x, y, z planes)
Veenema et al. (18)	University Orthodontic Department	30 subjects; Netherlands, pre- and post-treatment; permanent dentition; 5 Class I, 19 Class II div 1, 5 Class II div 2, 1 Class III; 5 treated with extractions.	Prospective, enrolled randomly	Digimodel/Digital callipers	2 (1)	ICON score
Leifert et al. (19)	University Orthodontic Department	25 subjects; USA, Class I molar relationship, crowding.	Prospective, enrolled consecutively	OrthoCad/Digital callipers	2 (1)	Crowding
Watanabe-Kanno et al. (20)	University Orthodontic Department	15 subjects; Brazil, permanent dentition; pre-treatment; 12–18 years.	Prospective	Cecile3/Digital callipers	2 (1)	Transverse dimensions; Tooth size; Overjet; Overbite
Horton et al. (21)	University Orthodontic Department	32 subjects; USA, permanent dentition; pre-treatment.	Prospective	Emodels/Digital callipers	1 (3)	Tooth size; Time taken

ABO, American Board of Orthodontics; PAR, Peer Assessment Rating.

Table 3. **Methodological quality of included studies using items from QUADAS (22)**

Study	Representative spectrum of patients	Reference standard appropriate	Adequate description of index test	Reference standard independent of index test	Adequate description of reference test	Results of index/reference test interpreted independently	Uninterpretable intermediate results reported
Tomassetti et al. (5)	Unclear	Yes	Yes	No	Yes	Unclear	No
Santoro et al. (6)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Bell et al. (7)	Unclear	Yes	Yes	No	Yes	Unclear	No
Quimby et al. (8)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Mayers et al. (9)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Costalos et al. (10)	Unclear	Yes	Yes	No	Yes	Unclear	No
Stevens et al. (11)	Yes	Yes	Yes	Yes	Yes	Unclear	No
Mullen et al. (12)	Unclear	Yes	Yes	No	Yes	Unclear	No
Okunami et al. (13)	Unclear	Yes	Yes	No	Yes	Unclear	No
Redlich et al. (14)	Unclear	Yes	Yes	No	Yes	Unclear	No
Hildebrand et al. (15)	Yes	Yes	Yes	No	Yes	Unclear	No
Goonewardene et al. (16)	Unclear	Yes	Yes	No	Yes	Unclear	No
Keating et al. (17)	Yes	Yes	Yes	No	Yes	Unclear	No
Veenema et al. (18)	Yes	Yes	Yes	No	Yes	Unclear	No
Leifert et al. (19)	Yes	Yes	Yes	No	Yes	Unclear	No
Watanabe-Kanno et al. (20)	Yes	Yes	Yes	No	Yes	Unclear	No
Horton et al. (21)	Unclear	Yes	Yes	No	Yes	Unclear	No

QUADAS, Quality Assessment of Studies of Diagnostic Accuracy included in Systematic Reviews.

21). A clear definition of the criteria used for entry into the studies was also omitted from these studies. Measurements were taken on both the index test and an appropriate reference standard in all studies with those on the plaster models performed independently of the digital models in all studies. In 13 studies, the index test and reference standard were not independent, both being derived from the same impression; separate impressions were taken in the remaining four studies (6, 8, 9, 11).

Blinded interpretation of results was precluded by obvious differences in the performance of digital and manual measurements. All investigations were performed prospectively, with sample size estimation reported in just five studies (7, 8, 11, 16, 17).

Results by outcome measures

Outcomes assessed include the validity of analysis of transverse dimensions; other miscellaneous linear measurements; tooth size; Bolton ratio; arch length and crowding; irregularity index; inter-arch occlusal features; occlusal indices; and time taken to perform measurements using the two approaches. No studies investigating the validity of angular measurements on digital models were found. The results are presented in Tables 4 and 5.

Transverse dimensional measurements

The agreement between transverse dimensional readings obtained using digital and plaster models has been assessed in four studies (7, 8, 16, 20). Dimensions considered include mandibular and maxillary inter-canine, inter-premolar and inter-molar dimensions. Mean discrepancies between the approaches ranged from 0.04 to 0.4 mm[8]. Generally, these differences were small and unlikely to be of clinical significance.

Miscellaneous linear measurements

The reliability of non-specific measurements between various defined occlusal landmarks with both sagittal and transverse components was investigated by Bell

Table 4. **Summary of results of comparison between digital models and plaster models**

Study	N*	Measurement	Digital model Mean (SD)	Plaster model Mean (SD)	Mean Difference† (p value, SE or CI)	Average of absolute mean differences† (SD)
Transverse dimensions‡ (mm)						
Quimby et al. (8)	1000	Maxillary IMW	54.72 (0.85)	54.43 (0.26)	0.29 ($p < 0.05$)	
		Maxillary ICW	36.04 (0.51)	36.44 (0.26)	−0.4 ($p < 0.05$)	
		Mandibular IMW	47.42 (0.52)	47.38 (0.33)	0.04 ($p < 0.05$)	
		Mandibular ICW	26.31 (0.27)	26.65 (0.24)	−0.34 ($p < 0.05$)	
Keating et al. (17)	60	ICW/IPMW/IMW			$p = 0.765$	0.19 (0.12)
Watanabe-Kanno et al. (20)	30	Maxillary ICW	34.23 (1.78)	34.35 (1.78)	−0.12 ($p < 0.001$)	
		Maxillary IPMW	34.52 (2.01)	34.63 (2.02)	−0.11 ($p < 0.001$)	
		Maxillary IMW	44.83 (2.54)	44.99 (2.54)	−0.16 ($p < 0.001$)	
		Mandibular ICW	26.57 (1.57)	26.71 (1.58)	−0.14 ($p < 0.001$)	
		Mandibular IPMW	28.73 (1.86)	28.86 (1.85)	−0.13 ($p < 0.001$)	
		Mandibular IMW	39.66 (2.25)	39.78 (2.25)	−0.12 ($p < 0.001$)	
Miscellaneous linear measurements (mm)						
Bell et al. (7)	176	Various transverse and sagittal measurements			$p > 0.05$	0.27 (0.06)
Keating et al. (17)	60	Y plane: Combined transverse and sagittal dimensions			$p = 0.501$	0.14 (0.09)
		Overall			$p = 0.237$	0.14 (0.1)
Tooth size (mm)						
Santoro et al. (6)	40	Overall mean			$p < 0.01$	−0.252
Redlich et al. (14)	90	Maxillary mean	7.73 (0.1§)	7.7 (0.12§)	0.03 ($p > 0.05$)	
		Mandibular mean	7.1 (0.1§)	7.11 (0.1§)	0.03 ($p > 0.05$)	
Goonewardene et al. (16)	50	Maxillary overall	76.1 (3.61)	74.8 (4)	1.3	
		Mandibular overall	66.3 (3.22)	65.7 (3.55)	0.6	
Watanabe-Kanno et al. (20)	30	21	8.76 (0.63)	8.94 (0.63)	−0.18 ($p = 0.6$)	
		26	9.9 (0.46)	10.1 (0.46)	−0.2 ($p = 0.00$)	
Horton et al. (21)	96	Overall difference			1.163 (0.115 per tooth)	
Keating et al. (17)	60	Crown height			0.03 ($p = 0.218$)	0.1 (0.07)
Bolton ratio (mm)						
Tomassetti et al. (5)	66	Anterior			1.02 ($p = 0.243$)	0.60 (0.38)
		Overall			1.2 ($p = 0.718$)	0.92 (0.58)
Stevens et al. (11)	360	Anterior	−0.55 (2.00)	−0.51 (1.80)	−0.04 ($p = 0.790$)	
		Overall	−0.75 (2.64)	−0.37 (2.20)	−0.38 ($p = 0.084$)	

Table 4. **Continued.**

Study	N*	Measurement	Digital model Mean (SD)	Plaster model Mean (SD)	Mean Difference† (p value, SE or CI)	Average of absolute mean differences† (SD)
Mullen et al. (12)	30	Overall			−0.05 (SE, 1.87; $p = 0.86$)	
Space analysis, arch length and tooth size–arch length discrepancy (crowding) (mm)						
Quimby et al. (8)	1000	Maxillary space available	74.87 (1.06)	73.58 (0.45)	0.29 ($p < 0.05$)	
		Maxillary space required	73.69 (0.93)	73 (0.37)	0.69 ($p < 0.05$)	
		Mandibular space available	65.71 (0.74)	64.02 (0.43)	1.69 ($p < 0.05$)	
		Mandibular space required	63.85 (0.86)	63.24 (0.49)	0.61 ($p < 0.05$)	
Stevens et al. (11)	360	Maxillary arch length	94.58 (5.25)	94.78 (5.33)	−0.20 ($p = 0.226$)	0.69 (0.43)
		Mandibular arch length	87.16 (5.44)	86.96 (5.17)	0.20 ($p = 0.256$)	0.65 (0.55)
Mullen et al. (12)	30	Maxillary arch length			1.47 (SE, 1.55; $p < 0.0001$)	
		Mandibular arch length			1.5 (SE, 1.36; $p < 0.0001$)	
Redlich et al. (14)	90	Maxillary arch length	73.45 (1.26)	73.64 (1.64)	−0.19 ($p > 0.05$)	
		Mandibular arch length	64.18 (1.29)	64.88 (1.22)	−0.7 ($p > 0.05$)	
		Maxillary crowding	1.41 (0.91)	1.77 (1.01)	−0.26 ($p > 0.05$)	
		Mandibular crowding	0.3 (0.92)	0.71 (0.92)	−0.41 ($p > 0.05$)	
Goonewardene et al. (16)	50	Maxillary arch length	75.8 (4.32)	74.8 (4.24)	1.0 ($p < 0.001$)	
		Mandibular arch length	65.9 (3)	65.1 (3.28)	0.8 ($p = 0.007$)	
		Maxillary crowding			−0.19 (SE = 0.219; $p = 0.38$)	
		Mandibular crowding			1.19 (SE = 0.23; $p < 0.000$)	
Leifert et al. (19)	50	Maxillary crowding	4.27 (2.41)	4.69 (2.46)	−0.424 (SE = 0.16; $p = 0.014$)	
		Mandibular crowding	3.69 (3)	3.9 (3.09)	−0.212 (SE = 0.23; $p = 0.364$)	
Irregularity index (mm)						
Stevens et al. (11)	360	Overall	23.7 (7.81)	20.99 (7.47)	2.71 ($p = .003$)	3.7 (3.05)

Table 4. **Continued.**

Study	N*	Measurement	Digital model Mean (SD)	Plaster model Mean (SD)	Mean Difference† (p value, SE or CI)	Average of absolute mean differences† (SD)
Goonewardene et al. (16)	50	Maxillary	7.8 (4.89)	7.8 (5.09)	0.0 ($p = 0.73$)	
		Mandibular	7.1 (3.07)	7.1 (3.19)	0.0 ($p = 0.13$)	
Inter-arch occlusal features (mm)						
Stevens et al. (11)	360	Centreline	1.23 (1.04)	1.32 (1.1)	−0.1 ($p = 0.30$)	0.34 (0.28)
		Posterior crossbite	0.75 (1.86)	0.74 (1.84)	0.01 ($p = 0.747$)	0.04 (0.12)
		Anterior crossbite	0.63 (0.98)	0.67 (1.09)	−0.03 ($p = 0.59$)	0.15 (0.26)
Santoro et al. (6)	40	Overjet			$p = 0.9771$	−0.00987
Quimby et al. (8)	1000		1.41 (0.4)	1.4 (0.21)	0.01 ($p > 0.05$)	
Stevens et al. (11)	360		4.91 (2.98)	4.9 (2.97)	0.01 ($p = 0.884$)	0.33 (0.21)
Watanabe-Kanno et al. (20)	30		5.22 (2.24)	5.43 (2.24)	−0.21 ($p = 0.00$)	
Santoro et al. (6)	40	Overbite			$p = 0.0124$	−0.4901
Quimby et al. (8)	1000		1.45 (0.53)	1.48 (0.3)	−0.03	
Stevens et al. (11)	360		3.67 (1.82)	3.96 (1.75) 3.51 (1.33)	−0.3 ($p = 0.01$)	0.38 (0.27)
Watanabe-Kanno et al. (20)	30		3.2 (1.32)		−0.31 ($p = 0.00$)	
Occlusal indices						
Veenema et al. (18)	60	Total ICON score (Examiner 1)	10.97 (2.47) 4.13 (1.31)	11.47 (2.37) 3.4 (1.07)	−0.5 0.73 ($p < 0.01$)	
Mayers et al. (9)	96	Overall PAR	27.25 (11.49)	27.35 (12.75)	−0.1 (ICC = 0.96–0.98)	
Stevens et al. (11)	360	score	25.91 (8.79)	25.08 (9.3)	0.83 ($p = 0.128$)	2.11 (1.62)
Time taken (min)						
Tomassetti et al. (5)	66	Bolton analysis	5.37 (0.87)	8.06 (0.54)	−2.69	
Mullen et al. (12)	30	Bolton analysis			$p < 0.001$	1.09 (47)
Horton et al. (21)	96	Occlusal view technique			−2.02	

*Number of determinations.
†Negative values represent smaller values on digital models.
‡ICW, Inter-canine width; IPMW, Inter-premolar width; IMW, Inter-molar width.
§SE. PAR, Peer Assessment Rating.

et al. (7) and Keating et al. (17). These studies described similar levels of consistency with mean discrepancies of 0.14 and 0.27 mm reported, respectively. Consequently, combinations of antero-posterior and transverse measurements appear to have similar reliability as purely transverse or sagittal measurements.

Tooth size

Differences in individual tooth size with digital and direct methods have been measured in the mesio-distal and vertical dimension. Tooth size has also been used indirectly to calculate Bolton tooth size ratios, arch length and tooth size–arch length discrepancy. Gener-

Table 5. **Summary of American Board of Orthodontics scoring**

	Study						
	Costalos et al. (10) (n = 24)			Okunami et al. (13) (n = 30)		Hildebrand et al. (15) (n = 36)	
Measurement technique/difference	Digital Mean (SD)	Plaster Mean (SD)	*p*	Mean diff.	*p*	Mean diff. (SD)	*p*
Alignment	5.42 (3.11)	7.75 (3.89)	<0.0001	0.23	0.34	0.61 (0.8)	<0.01
Marginal ridges	3.67 (2.48)	4 (2.6)	0.4694	0.03	0.837	0.28 (0.57)	0.11
Inclination	5.67 (1.81)	6.71 (3.06)	0.0507	n/a	n/a	0.28 (0.51)	0.571
Occlusal contacts	6.54 (4.24)	5.33 (5.31)	0.2169	−4.53	0.000	1.89 (2.48)	0.021
Occlusal relationships	1.83 (1.97)	2.17 (2.63)	0.3567	−0.5	0.023	0.11 (0.4)	0.422
Overjet	6.25 (3.42)	4.67 (2.75)	0.1077	−0.37	0.1	3.94 (2.65)	<0.001
Interproximal contacts	0.29 (0.62)	0.75 (1.22)	0.0613	−0.13	0.102	0.03 (0.17)	0.324
Overall	29.67 (9.29)	31.17 (10.47)	0.3467	−5.07	0.000	9 (5.54)	<0.01

*Negative values represent smaller values on digital models.

ally, minor mean differences in mesio-distal tooth dimension of 0.01–0.3 mm were reported overall (6, 14, 16, 20, 21).

Measurement of vertical crown height is likely to be imprecise with identification of a cervical point particularly unreliable. Keating et al. (17) assessed vertical crown heights of premolars and molars using the maximum point of concavity on the labial surface gingival margin as the cervical reference point; a difference in the measurement of canine and molar heights of 0.1 mm was detected.

Bolton ratio

Comparison of Bolton tooth size analyses has been performed on digital and plaster models (5, 11, 12). Acceptable agreement between the two methods was demonstrated in all three studies. Stevens et al. (11) described an anterior discrepancy of 0.6 mm; however, Mullen et al. (12) reported an overall mean difference of just 0.05 mm. Stevens et al. (11) found an overall discrepancy of 0.38 mm using emodels; Tomassetti et al. (5) found a more significant difference of 1.02–1.2 mm between direct measurement on plaster models and digital measurement using OrthoCad.

Space analysis, arch length and tooth size–arch length discrepancy (crowding)

Overall, arch length, crowding and space analysis were measured in five studies (8, 11, 14 16, 19). With respect to arch length, discrepancies between the techniques ranged from 0.19 (14) to 0.8 mm (16). The difference between the measurement of crowding obtained with the techniques varied from 0.19 mm (16) to 0.42 mm (19); however, the mean degree of crowding in each trial did not exceed 4.69 mm (19), with the arches being spaced in one of the studies (16).

Irregularity index

The irregularity index in both the maxillary and mandibular arches was measured by Goonewardene et al. (16). Identical mean levels of irregularity were calculated with both techniques using OrthoCad digital models. However, using emodels, Stevens et al. (11) reported a significant discrepancy with the digital software underestimating irregularity by 3.7 mm.

Inter-arch occlusal features

Agreement between measurement of overjet and overbite has been considered in four studies (6, 8, 11, 20). Quimby et al. (8) and Watanabe-Kanno et al. (20) reported near-perfect agreement for both parameters; similarly, Santoro et al. (6) and Stevens et al. (11) showed excellent agreement for overjet measurement. The concordance of measurement of posterior crossbite and centreline discrepancy was confirmed by Stevens et al. (11). Inter-arch features including buccal segment interdigitation, overbite and overjet are also considered as part of occlusal indices including PAR, ICON and ABO scoring.

Occlusal indices

Acceptable concordance with digital and plaster models in relation to the severity of malocclusion using PAR, ICON and ABO scores has been demonstrated. The agreement between manual and digital measurements was high with respect to both PAR (9, 11) and ICON (18). In relation to the ABO score, three studies (10, 13, 15) reported comparisons between the techniques. In general, the differences between the measurement methods are low; however, Okunami et al. (13) and Costalos et al. (10) reported a significant discrepancy with respect to occlusal contact and buccolingual inclination scores. Furthermore, Costalos et al. (10) reported a significant difference in arch irregularity. These discrepancies were attributed to limitations pertaining to one software program (OrthoCad™); the ABO method of measuring inclination is also difficult to apply to digital models.

Time taken

The difference in the time required to perform a variety of occlusal measurements has been assessed in three disparate studies (5, 12, 21). These studies suggest a significant time saving with digital techniques although a significant learning curve and period of adjustment are likely to be required. Relatively minor differences were described by Horton et al. (21) (2 min) and Mullen et al. (12) (1 min). The approach to digital measurement is also believed to have an impact, with manipulation of the model being necessary to perform specific measurements. Differences may also arise in view of software and familiarity with the technique; Mullen et al. (12) used the widely available emodels™. Horton et al. (21) measured time taken to calculate tooth dimensions in isolation, and Mullen et al. (12) calculated Bolton tooth size ratios.

Discussion

Earlier research has confirmed that digital software is capable of faithfully reproducing dental features with a high degree of accuracy (2, 23–31). This research was omitted from this review as our main focus was to ascertain whether digital models offer a valid and clinically useful alternative to plaster models.

The application of digital models in orthodontic practices has increased steadily with 18% of surveyed practitioners reporting usage in a recent survey in the United States (32). This development has been prompted by a range of perceived advantages including reduced storage requirements; rapid access to digital information; easy transfer of data; versatility; and financial savings. This systematic review confirms that these proven advantages occur without significant compromise to the reliability of occlusal information.

To analyse the validity of digital models, plaster models were chosen as a reference standard in this review as direct measurement is performed on plaster models with rulers or callipers routinely in orthodontic offices and for research purposes. However, direct measurement on plaster models is inevitably associated with some degree of inaccuracy. To produce a more accurate 'gold standard', researchers have developed artificial models permitting more accurate measurement (8, 12) or have compared measurements between artificial structures of known dimension (33). Generally, digital models have shown a high degree of accuracy using these techniques (12). Much of the error of the measurement technique is likely to reside in point identification rather than being a function of the measuring device or software. Therefore, with enhancement of direct digital superimposition techniques and digital point recognition, digital modelling may replace plaster models as the 'gold standard'.

Evidence for the validity of digital models as an alternative to plaster models is accumulating. However, the methodological quality of studies included in this review was variable. In particular, description of the sample population was inadequate. Furthermore, separate impressions were used to fabricated digital and plaster models in four of the included studies. Differences in the impressions and casting processes may therefore have contributed to some of the inconsistency reported in these trials (6, 8, 9, 11). Complete data on the absolute differences between the techniques including confidence intervals and standard errors were also rarely reported. Further studies in this area should refer to QUADAS guidelines (22) and would benefit from clear reporting of the patient sample on which the models are based and independent interpretation of results.

This systematic review involved assessment of publications from English-language and non-English-language databases. Unpublished data were also searched. Consequently, it was felt that most data have been accessed. Where possible, complete results were obtained from these studies. Studies were excluded if there was a time lag between taking the impressions and pouring study models, where artificial occlusal setups were used and when models were marked before measurement (Appendix 1). However, although not considered formally in this review, the results of these studies appeared to be in general agreement with those of the included research studies.

Overall, the mean discrepancy between measurement based on digital and plaster models was low. The differences were considered in all studies to be clinically insignificant. This finding has been corroborated by studies demonstrating excellent concordance of treatment-planning decisions based on digital and plaster models (34, 35). Replacement of plaster with digital models resulted in diagnostic changes in 13%, translating into alteration of the treatment plan in just 6% of cases (34). This discrepancy is in keeping with research highlighting inconsistency in orthodontic planning decisions by the same and different clinicians, irrespective of differences in records available (36–38).

A further potential advantage of digital models lies in the ability to measure tooth position in three dimensions. In particular, measurement of inclination of individual teeth on plaster models is unreliable and cumbersome. However, digital models may be manipulated and sectioned to analyse specific teeth and permit estimation of long axis position. Furthermore, three-dimensional mapping of tooth movement may be possible by superimposing dental changes on stable reference structures with use of non-destructive digital manipulation and sectioning techniques.

Conclusions

Digital models offer a high degree of validity when compared to direct measurement on plaster models; differences between the approaches are likely to be clinically acceptable.

Clinical relevance

Digital models are gaining increasing acceptance as an alternative to traditional plaster models in orthodontics. The potential advantages of digital models would be negated if the validity, efficiency and ease of linear and angular measurement with digital models were not comparable to those related to plaster models, the current 'gold standard' used routinely in clinical practice. This review confirms that digital models offer a valid alternative to plaster models, although the available evidence is of variable quality.

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ORIGINAL ARTICLE

AJO-DO

Comparison of maxillary arch dimensional changes with passive and active self-ligation and conventional brackets in the permanent dentition: A multicenter randomized controlled trial

Padhraig S. Fleming,[a] Robert T. Lee,[b] Valeria Marinho,[c] and Ama Johal[a]
London, United Kingdom

Introduction: The purpose of this study was to compare maxillary arch dimensional and inclination changes during alignment with conventional brackets and self-ligation. **Methods:** Ninety-six patients, ages 16 years and above, were included in this multicenter, 3-group parallel randomized trial. The main outcome measures were changes in maxillary intercanine, interpremolar, and intermolar dimensions, and molar and incisor inclination changes. The patients were randomly allocated in permuted blocks of 12 subjects into 3 equal groups with the allocations concealed in opaque sealed envelopes. Each participant underwent alignment with a standard Damon Q (Ormco, Orange, Calif) wire sequence for a minimum of 34 weeks. Blinding of clinicians and patients was not possible. Data were analyzed on a per-protocol basis, since losses to follow-up were minimal. **Results:** Complete data were obtained from 87 subjects. Bracket type had no significant effect on any of the transverse dimensional changes. No difference in molar inclination was found between passive self-ligation and conventional brackets (0.67°; 95% CI, −2.24, 3.58; P = 0.65) or active self-ligation (0.91°; 95% CI, −1.95, 3.78; P = 0.53). Similarly, incisor inclination changes with the Damon Q could not be differentiated from those developing with either conventional system (0.44°; 95% CI, −1.93, 2.8; P = 0.71) or In-Ovation C (−0.22°; 95% CI, −2.58, 2.14; P = 0.85). No harms were encountered. **Conclusions:** No difference in the arch dimensional or inclination changes during alignment can be expected between conventional brackets and either active or passive self-ligation. (Am J Orthod Dentofacial Orthop 2013;■:■-■)

The desire to treat patients on a nonextraction basis has been a persistent quest punctuated by apparent success,[1] by resignation to failure,[2] and recently by renewed fervor.[3] Among the techniques and mechanics with the potential to facilitate nonextraction treatment are headgears, fixed sagittal correctors, and self-ligating brackets. Although each of these approaches necessitates an increase in arch length to produce alignment without extraction, it has been purported that passive self-ligating brackets can introduce specific, uniquely stable arch dimensional changes.[4]

Self-ligating brackets have been advanced as a technique to streamline clinical procedures and reduce overall treatment time. However, although there is limited evidence proving clinical time savings[5] and advantages relating to inventory requirements and chair-side assistance, there is a lack of evidence suggesting shorter treatment times with these systems.[6-9] Nevertheless, the belief that these brackets expedite treatment and facilitate nonextraction approaches is firmly held by many clinicians.[10] It has been claimed that passive self-ligating brackets promote posterior expansion without concomitant labial movement of the incisors; this claim has not, however, been made about

From Barts and the London School of Medicine and Dentistry, London, United Kingdom.
[a]Senior clinical lecturer and honorary consultant, Queen Mary University of London, Institute of Dentistry.
[b]Honorary professor and consultant, Barts Health Trust.
[c]Senior lecturer, Queen Mary University of London, Institute of Dentistry.
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Reprint requests to: Padhraig S. Fleming, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, Institute of Dentistry, Turner St, London E1 2AD, United Kingdom; e-mail, padhraig.fleming@gmail.com.
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active self-ligating brackets in which the clip encroaches on the archwire during the later stages of alignment. Previous randomized trials comparing arch dimensional changes with self-ligating and conventional systems have been restricted to the mandibular arch.[11-14] These trials have also been equivocal, with 2 studies reporting statistically greater amounts of intermolar expansion with self-ligating systems.[11,13]

It is widely accepted that both the magnitude and the nature of arch dimensional changes have an influence on prolonged stability. In particular, widening of the mandibular intercanine dimension is regarded as unstable.[15] Similarly, tipping movements are typically impermanent.[16] Moreover, there are defined limits to the dentition and negative esthetic connotations of excessive maxillary incisor proclination. Consequently, in many cases, a panacea would involve posterior bodily expansion with little change in incisor position.

The aims of this randomized controlled trial were therefore to quantify maxillary arch dimensional changes and maxillary incisor and molar inclination changes during orthodontic alignment by directly comparing a passive self-ligating bracket (Damon Q; Ormco, Orange, Calif), an active self-ligating system (In-Ovation C; Dentsply GAC International, Islandia, NY), and a conventional bracket system (Ovation, Dentsply GAC International).

MATERIAL AND METHODS

Ethical approval for this multicenter, 3-arm, parallel-group randomized trial was obtained from the Cambridgeshire 1 research ethics committee in the United Kingdom (09/H0304/45). Participants were recruited from the orthodontic treatment waiting lists from April 2009 to June 2011 at East Kent Hospitals, Royal London Dental Institute, and Southend NHS Foundation Trust. The patients were given written and verbal explanations about the study. Those agreeing to participate completed a written consent form.

Based on previous research, 81 participants (27 in each group) were required with a power of 90% to detect a minimum difference of 1 mm (SD, 1 mm) between the largest and the smallest means among the 3 groups in intermolar width changes at the 0.05 level of statistical significance.[11] To compensate for attrition of the sample and to enhance statistical power, a further 15 subjects (18.75%) were recruited, culminating in a total sample of 96 subjects. The power calculation was performed with Stata software (version 12.1; StataCorp, College Station, Tex) by using the *fpower* command for 1-way analysis of variance (ANOVA) power analysis.

The following selection criteria were applied. The inclusion criteria were (1) young adults 16 years of age and over; (2) fit and healthy, and taking no medication; (3) in the permanent dentition with the maxillary second molars erupted; (4) maxillary arch crowding less than 6 mm; and (6) amenable to nonextraction treatment in the maxillary arch. The exclusion criteria were (1) cleft lip and palate, and other craniofacial anomalies; (2) previous orthodontic treatment; (3) complex medical history and taking medications; and (4) congenital absence of teeth in the maxillary arch other than third molars.

All participants had study models and lateral cephalograms taken not more than 1 month before placement of the fixed appliance. An unpredictable, stratified subject allocation sequence was generated by using an electronic randomization program with stratified randomization for each center. Randomization was carried out in random permuted blocks of 12 patients in a ratio of 1:1:1. The assignment of each subject was implemented by 1 researcher (P.S.F.) and concealed from the clinician until the appointment at which the appliance was to be placed in sequentially numbered, opaque, and sealed envelopes. Corresponding envelopes were opened only after the participants completed all baseline assessments and were due to commence active treatment. The visibility of the orthodontic appliances precluded blinding of either the operator or the participant to the allocated arm during treatment. However, outcome assessors and data analysts were blind to the appliance type during data analysis.

Self-ligating preadjusted edgewise brackets (Damon Q and In-Ovation C) with Roth values for tip and torque and 0.022-in slots were placed in the intervention groups, and Ovation was used in the comparison group in the maxillary arch based on the random allocation procedure. A 0.013-in or 0.014-in round copper-nickel-titanium archwire (Damon; Ormco) of uniform arch form was placed in all patients with attachments placed on all teeth from the maxillary second molar to second molar. The conventional twin brackets were ligated with elastomeric modules. Areas with marked irregularity in the group with conventional brackets were tied with elastomerics in a figure-eight configuration or with stainless steel ligatures to permit complete engagement. Subjects underwent treatment with a predetermined Damon archwire sequence comprising 0.013-in or 0.014-in round copper-nickel-titanium, 0.014 × 0.025-in copper-nickel-titanium, 0.018 × 0.025-in copper-nickel-titanium, and 0.019 × 0.025-in stainless steel. All wires had Damon arch form and were uncoordinated to the original arch form or dimensions. The nickel-titanium wires were changed after intervals of 10, 10, and 6 weeks, respectively. The

0.019 × 0.025-in stainless steel wire was left in place for a minimum of 8 weeks. In relation to the maxillary fixed appliance, the archwire was cut distal to the second molar tube; the wire was not cinched distally. No bite planes, palatal arches, quad-helices, palatal expanders intermaxillary elastics, or headgear to the maxillary arch were used during the study period. All operators were given a copy of the treatment protocol before treatment. In cases of appliance breakage, every effort was made for the patient to be seen by a principal operator. If it was deemed impossible to religate a wire of the same dimension, this wire was replaced with a narrower wire within the wire sequence used throughout the study.

Alginate impressions of the maxillary arch were taken before treatment and at the end of alignment, a minimum of 34 weeks after appliance placement, when a 0.019 × 0.025-in stainless steel archwire was engaged passively. Models were measured as serial pairs and numbered for identification purposes with brackets obscured with wax on the posttreatment models during measurement. Measurements were made consecutively on each cast by an examiner (P.S.F.). Cephalograms taken before treatment and after arch alignment and leveling were traced.

The following transverse dimensions were recorded with digital calipers (150 mm ISO 9001 electronic caliper; Tesa Technology, Renens, Switzerland): (1) intercanine width, the distance between the maxillary canine cusp tips; (2) interpremolar widths, the distances between the buccal cusp tips of both the maxillary first and second premolars; and (3) intermolar width, the distance between the mesiobuccal cusp tips of the maxillary first molars.

The measurements were made in duplicate, and the average of the 2 readings was taken to a resolution of ±0.01 mm. The maxillary arch was viewed from above, and the calipers were held parallel to the occlusal plane. The degree of crowding on each model was determined by measuring the combined mesiodistal widths of the teeth from the mesial aspect of the first molar to the mesial aspect of the first molar (space required) and subtracting the arch perimeter (space available).

The gypsum reference models were digitized by using a scanner (AR250; 3Shape, Copenhagen, Denmark) comprising high-resolution charge-coupled device cameras, a laser projector, and an articulating table. The digital models were subsequently viewed and measured with proprietary software, by using a magnifying function (Orthoanalyzer; 3Shape).

To improve the validity and reproducibility of estimation of the long axis of the teeth, opaque white polymethyl methacrylate caps with a flat upper surface were fabricated and fitted to the maxillary first

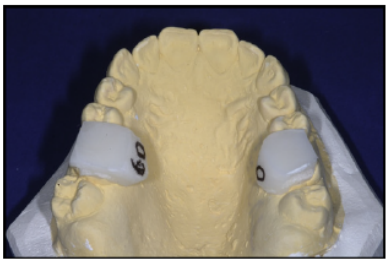

Fig 1. White acrylic caps on the maxillary first molars t facilitate measurement of molar inclination changes.

permanent molars. The acrylic extended approximatel 5 mm above the palatal and occlusal surfaces, and projected onto the buccal surface to withstand rotation o the model during the scanning process. The acrylic jig were covered with an opaque sealer to prevent light penetration and involution of the jig on the resultant image opaque stickers were added to the upper surface for th same reason while preserving the flat surface (Fig 1] When necessary, before fabrication, marked occlusal fissures were blocked out with wax to permit a reproducibl fit. Angular measurements were made by using a splicin function with the Orthoanalyzer software, visualizin the virtual models from the front or the rear view, which ever was thought to be more clear (Fig 2). The orientation in which the model was measured was recorded and this view was maintained during measurement o both pretreatment and posttreatment models.

In addition, 10 models were also scanned afte removal and replacement of the jigs on the first molars This permitted assessment of both the reproducibility o the measurement technique and the fit and placement o the jigs. The reproducibility of the technique wa confirmed by repeating the measurements in randon order 2 weeks after the initial readings, with a mea difference of 0.51° (SD, 2.01°) and 95% Bland-Altma limits[17] of −3.42 and 4.45.

Angular changes in axial inclination of the long axi of the maxillary incisor relative to the maxillary plan were measured by assessing both lateral cephalograms Radiographs were traced and measured as serial pairs.[1] Two sets of readings were obtained for each measurement and their values averaged. Individual angles wer retraced if differences between the values exceeded 5° Maxillary incisor inclination was measured to a toleranc of 0.5°.

Statistical analysis

A descriptive summary of baseline demographic an clinical characteristics of participants in the study wa

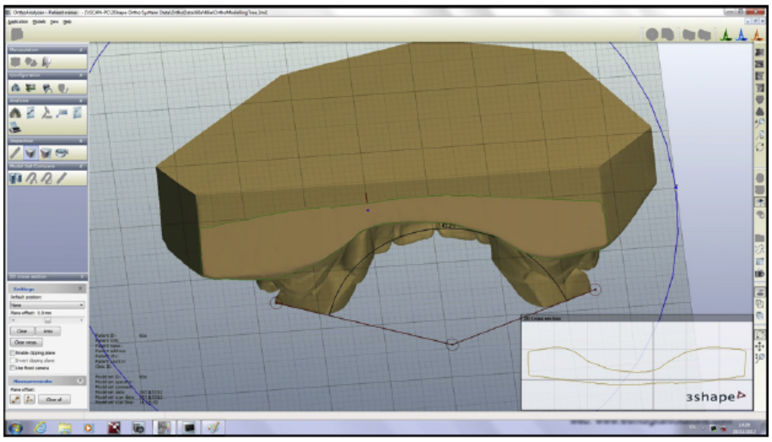

Fig 2. Method for measuring molar inclination change with Orthoanalyzer software.

undertaken (Table I) including sex, ethnicity, age, malocclusion, operator, crowding, and baseline inclination for each bracket system. Analysis of covariance (ANCOVA) was used to compare the influence of the 3 bracket systems on the transverse dimensional changes and the incisor and buccal segment inclination changes. Separate analyses were conducted for canines, premolars, and molars. Pretreatment crowding and pretreatment scores for incisor inclination or transverse dimensions were treated as covariates in the analysis to allow for differences in these potential confounders. An exploratory assessment of the effect of pretreatment intercanine dimensions on expansion of the maxillary interfirst premolar, intersecond premolar, and intermolar widths was also undertaken. Assumptions for linear regression were assessed by plotting residuals. All statistical analyses were conducted with Stata statistical software with a prespecified level of statistical significance of $P < 0.05$.

RESULTS

Overall, 101 participants were recruited; of these, 96 received an intervention. Nine participants had missing data; however, the data were analyzed on a per-protocol basis, since the attrition rate was relatively minor and unlikely to be attributable to bracket design (Fig 3). There was little difference between the 3 groups in terms of demographic characteristics (Table I). There were slightly more male (n = 49, 51%) than female subjects. The majority were white subjects (n = 81, 84%). The participants represented a wide range of malocclusions with a large proportion of Class III cases (n = 42, 44%). Overall, there were 8 operators, although most participants were treated by the first author (P.S.F.) (n = 73, 76%). Subjects in the In-Ovation group were slightly older than those in the other groups, with their mean overall age 20 years. The degree of crowding in all 3 groups was mild (mean, 2.48 mm; SD, 2.28).

Intercanine dimensions increased in all 3 groups, with slightly greater increases in the Damon Q group (Table II). A slightly smaller increase in intercanine width arose with both In-Ovation C (−0.19 mm; 95%CI, −0.95, 0.57; $P = 0.62$) and Ovation (−0.66 mm; 95% CI, −1.44, 0.12; $P = 0.10$) compared with Damon Q after adjusting for initial intercanine width and pretreatment crowding. Those differences did not reach statistical significance. In the adjusted analysis, initial intercanine width was a significant predictor of the posttreatment value (β, 0.45; 95% CI, 0.34, 0.56; $P < 0.01$), whereas a significant effect of pretreatment crowding was not identified (β, 0.02; 95 CI%, −0.16, 0.11; $P = 0.73$).

Similarly, the interfirst premolar and intersecond premolar dimensions increased considerably in all 3 groups; however, no association was found between appliance type and posttreatment interpremolar width after adjusting for baseline differences in interpremolar dimensions and crowding (Table III). In the adjusted model, both crowding and pretreatment interpremolar dimensions were found to be significant predictors of the posttreatment scores with the final intersecond premolar dimension increasing by 0.4 mm for each millimeter of crowding (β, 0.4; 95% CI, 0.26, 0.54; $P < 0.01$).

Table I. Demographic and clinical characteristics of the sample (n = 96)

	Appliance			
	Damon Q n (%) or mean (SD)	*In-Ovation C n (%) or mean (SD)*	*Ovation n (%) or mean (SD)*	*Overall n (%) or mean (SD)*
Site				
East Kent Hospitals	21 (66)	22 (69)	22 (69)	65 (68)
Royal London Dental Institute	11 (34)	10 (31)	8 (25)	29 (30)
Southend NHS Foundation Trust	0 (0)	0 (0)	2 (6)	2 (2)
Sex				
Male	14 (44)	14 (44)	21 (66)	49 (51)
Female	18 (56)	18 (56)	11 (34)	47 (49)
Ethnicity				
White	26 (81)	27 (84)	28 (88)	81 (84)
Asian Caucasian	5 (16)	3 (9)	2 (6)	10 (10)
Afro-Caribbean	1 (3)	2 (2)	1 (3)	4 (4)
Oriental	0 (0)	0 (0)	1 (3)	1 (4)
Malocclusion				
Class I	9 (28)	5 (16)	6 (19)	20 (21)
Class II Division 1	7 (22)	8 (25)	8 (25)	23 (24)
Class II Division 2	1 (3)	9 (28)	1 (3)	11 (11)
Class III	15 (47)	10 (31)	17 (53)	42 (44)
Operator				
1	24 (75)	27 (84)	22 (69)	73 (76)
2	2 (6)	3 (9)	2 (6)	7 (7)
3	4 (13)	0 (0)	1 (3)	5 (5)
4	2 (6)	0 (0)	2 (6)	4 (4)
5	0 (0)	0 (0)	1 (3)	1 (1)
6	0 (0)	2 (6)	1 (3)	3 (3)
7	0 (0)	0 (0)	1 (3)	1 (1)
8	0 (0)	0 (0)	2 (6)	2 (2)
Age (y)	18.9 (2.9)	22.5 (8.5)	18.6 (3.4)	19.7 (5.9)
Crowding (mm)	2.3 (2.64)	2.59 (1.99)	2.56 (2.22)	2.47 (2.28)
Maxillary transverse dimensions (mm)				
Intercanine	32.21 (3.07)	32.64 (2.89)	33.5 (2.64)	32.91 (2.88)
Interfirst premolar	38.01 (3.5)	38.94 (3.61)	39.42 (2.64)	38.9 (3.67)
Intersecond premolar	44.16 (3.66)	43.95 (3.55)	44.72 (3.73)	44.13 (3.63)
Intermolar	49.36 (3.62)	49.06 (4.26)	50.02 (3.5)	49.48 (3.79)
Maxillary incisor inclination (°)	112.5 (6.47)	109.25 (6.73)	111.25 (7.23)	111.24 (6.94)
Total	32 (100)	32 (100)	32 (100)	96 (100)

Increases in intermolar dimension occurred relatively uniformly in all 3 groups (Table II, Fig 4); however, the [F4-4/C] magnitude of changes was less than that arising in the maxillary premolar dimensions. Mean increases of just 1.22 mm arose in intermolar width with Damon Q. After accounting for pretreatment differences and crowding in the adjusted model (Table III), no difference could be detected between intermolar width with Damon Q and In-Ovation C (β, 0.40; 95% CI, −0.31, 1.11; $P = 0.27$) or Damon Q and the conventional system (β, 0.32; 95% CI, −0.41, 1.05; $P = 0.38$). As with other transverse changes, both initial intermolar width (β, 0.68; 95% CI, 0.60, 0.75; $P < 0.01$) and crowding (β, 0.21; 95% CI, 0.08, 0.34; $P < 0.01$) were found to have a significant influence on transverse changes in the adjusted model (Table III).

In the unadjusted model, the mean increase in maxillary incisor inclination ranged from 1.12° (Damon Q) to 3.25° (In-Ovation C). After accounting for pretreatment scores and crowding in the adjusted model, no statistical difference in incisor inclination could be found between either Damon Q and In-Ovation C (β, −0.22 mm; 95% CI, −2.58, 2.14; $P = 0.85$) or Damon Q and Ovation (β, 0.44 mm; 95% CI, −1.93, 2.8; $P = 0.71$). Pretreatment maxillary incisor inclination (β, 0.53; 95% CI, 0.38, 0.67; $P < 0.01$) and pretreatment crowding (β, 0.47; 95% CI, 0.03, 0.90; $P < 0.04$) were both significant predictors of posttreatment maxillary incisor values. Little change in molar inclination was observed in the 3 groups. Overall, a small amount of increased buccal crown inclination was found; the degree of buccal flaring was slightly greater

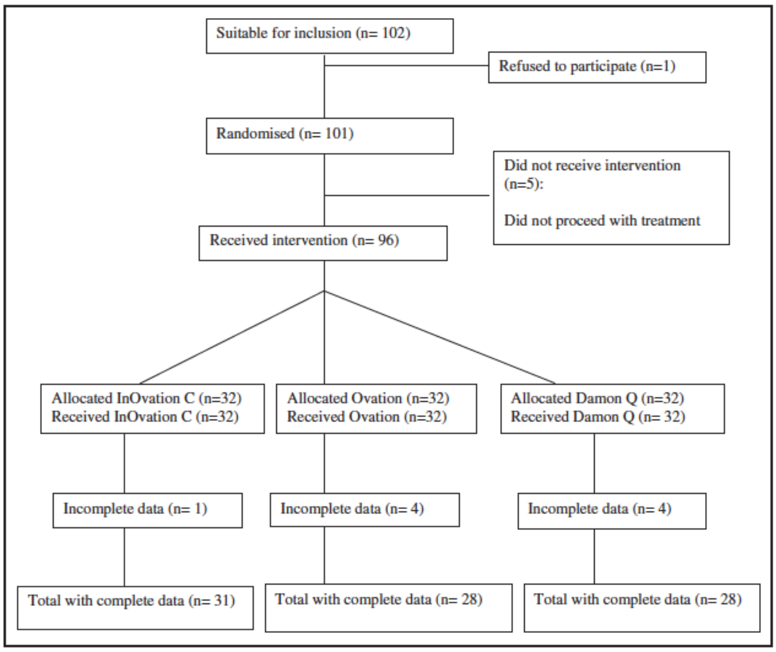

Fig 3. CONSORT diagram showing the flow of participants through the trial.

Table II. Maxillary transverse dimensions and incisor inclination before and after alignment

	Appliance		
	Damon Q mean (SD)	*In-Ovation C mean (SD)*	*Ovation mean (SD)*
Pretreatment maxillary transverse dimensions (mm)			
Intercanine	32.64 (3.07)	32.64 (2.89)	33.5 (2.64)
Interfirst premolar	38.37 (3.45)	38.94 (3.61)	39.42 (4.01)
Intersecond premolar	43.76 (3.66)	43.95 (3.55)	44.72 (3.73)
Intermolar	49.41 (3.62)	49.06 (4.26)	50.02 (3.5)
Posttreatment maxillary transverse dimensions (mm)			
Intercanine	34.62 (1.85)	34.42 (2.2)	34.38 (1.85)
Interfirst premolar	42.88 (1.87)	42.7 (2.46)	43.18 (2.08)
Intersecond premolar	47.61 (2.25)	47.73 (2.83)	48.31 (2.43)
Intermolar	50.68 (2.32)	50.87 (3.39)	51.48 (2.9)
Change in maxillary transverse dimensions (mm)			
Intercanine	1.97 (2.16)	1.78 (2.21)	0.88 (2.18)
Interfirst premolar	4.51 (2.68)	3.75 (2.31)	3.7 (3.19)
Intersecond premolar	3.96 (2.51)	3.78 (1.91)	3.59 (2.8)
Intermolar	1.22 (2.26)	1.82 (1.59)	1.41 (2.08)
Change in maxillary first molar inclination (°)	−2.04 (5.90)	−1.38 (5.08)	−1.36 (5.66)
Pretreatment maxillary incisor inclination (°)	113.28 (6.47)	109.25 (6.73)	111.25 (7.23)
Posttreatment maxillary incisor inclination (°)	114.83 (5.79)	112.49 (5.34)	114.26 (5.94)
Change in maxillary incisor inclination (°)	1.12 (3.88)	3.25 (6.89)	2.84 (5.68)
Total (n)	32 (100)	32 (100)	32 (100)

in the Damon Q group, with 0.66° more change than with In-Ovation C (Table II). However, this difference did not have statistical significance (β, 0.91; 95% CI, −1.95, 3.78; P = 0.53; Fig 5). Similarly, slightly [F5- more molar flaring was observed in the Damon Q group than with Ovation; however, the difference did not

Table III. Coefficients and associated 95% confidence intervals (CIs) for the effect of appliance type on outcome variables (transverse dimensions, incisor and molar inclination changes)

Outcome	*Variable*	*Category*	*β (95% CI)*	*P value*
Intercanine width	Appliance	Damon Q	Reference	
		In-Ovation C	−0.19 (−0.95, 0.57)	0.62
		Ovation	−0.66 (−1.44, 0.12)	0.10
	Initial intercanine width	Per unit (mm)	0.45 (0.34, 0.56)	<0.01
	Crowding	Per unit (mm)	−0.02 (−0.16, 0.11)	0.73
Interfirst premolar width	Appliance	Damon Q	Reference	
		In-Ovation C	−0.19 (−1.27, 0.21)	0.16
		Ovation	−0.29 (−1.05, 0.47)	0.45
	Initial interfirst premolar width	Per unit (mm)	0.46 (0.37, 0.55)	<0.01
	Crowding	Per unit (mm)	0.27 (0.13, 0.41)	<0.01
Intersecond premolar width	Appliance	Damon Q	Reference	
		In-Ovation C	−0.16 (−0.88, 0.56)	0.66
		Ovation	−0.05 (−0.79, 0.69)	0.89
	Initial intersecond premolar width	Per unit (°)	0.62 (0.53, 0.70)	<0.01
	Crowding	Per unit (mm)	0.40 (0.26, 0.54)	<0.01
Intermolar width	Appliance	Damon Q	Reference	
		In-Ovation C	0.40 (−0.31, 1.11)	0.27
		Ovation	0.32 (−0.41, 1.05)	0.38
	Initial intermolar width	Per unit (°)	0.68 (0.60, 0.75)	<0.01
	Crowding	Per unit (mm)	0.21 (0.08, 0.34)	<0.01
Maxillary incisor inclination	Appliance	Damon Q	Reference	
		In-Ovation C	−0.22 (−2.58, 2.14)	0.85
		Ovation	0.44 (−1.93, 2.80)	0.71
	Initial maxillary incisor inclination	Per unit (°)	0.53 (0.38, 0.67)	<0.01
	Crowding	Per unit (mm)	0.47 (0.03, 0.90)	<0.04
Maxillary molar inclination	Appliance	Damon Q	Reference	
		In-Ovation C	0.91 (−1.95, 3.78)	0.53
		Ovation	0.67 (−2.24, 3.58)	0.65
	Initial inclination	Per unit (mm)	−0.06 (−1.7, 0.05)	0.32

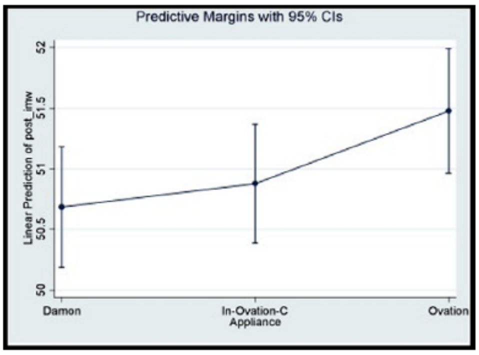

Fig 4. Predictive margins and associated 95% confidence intervals of final intermolar dimensions with type of appliance.

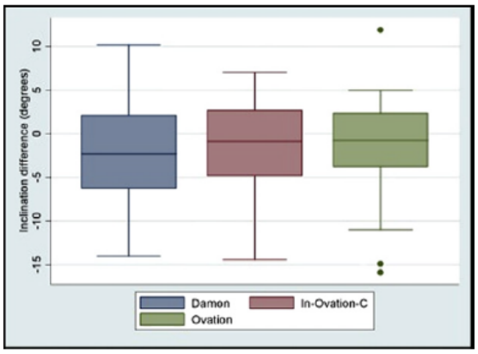

Fig 5. Box plots showing the medians and ranges of values of inclination differences with each fixed appliance system. Negative values denote buccal flaring of the maxillary molars.

reach statistical significance (β, 0.67; 95% CI, −2.24, 3.58; $P = 0.65$).

Pairwise correlation demonstrated a positive correlation between pretreatment intercanine dimensions and increases in transverse dimensions posteriorly ($P < 0.01$). The correlation coefficients between pretreatment intercanine dimensions and interfirst premolar, intersecond premolar, and intermolar widths were 0.63, 0.67, and 0.65, respectively.

DISCUSSION

Although self-ligating brackets have gained increasing popularity in the United States and abroad, a series of clinical trials has failed to galvanize this trend with supporting evidence. Repeated claims of more efficient treatment have been made; these have been contradicted by the findings from 3 randomized trials.[7-9] Similarly, there appears to be little basis for the claim that self-ligating brackets induce distinctive arch dimensional changes. In this study, we have confirmed that arch dimensional changes with both passive and active self-ligation cannot be differentiated from those of conventional systems. Similarly, whereas relative restraint of the maxillary incisors during alignment has been attributed to passive self-ligation, this concept was not borne out in this investigation with marginal advancement of the maxillary incisors from all 3 systems.[6]

The magnitude of expansion recorded in our study was in keeping with previous prospective investigations.[19,20] Significant changes occurred in the premolar region with up to 4.51 mm of expansion with Damon Q in the first premolar region. The changes were slightly greater than those reported by Franchi et al[19] in a prospective follow-up of 20 patients treated with fixed appliances with low-friction ligatures over the initial 6 months of appliance therapy. Franchi et al reported expansion ranging from 1.71 to 3.65 mm for maxillary transverse dimensions with increases peaking in the premolar region. Intermolar expansion of 1.71 mm comprised both bodily movement and tipping with 4.33° of buccal flaring.[17] Slightly greater changes were reported in an observational study by Begole et al.[20] The reasons for relatively large dimensional increases in our study might relate to the use of Damon archwires, whereas Tru-arch medium-form wires were used by Franchi et al. Damon wires have a broad arch shape, particularly in the buccal segments, and could have contributed to the amount of expansion reported. To definitively prove this, however, would require further prospective research. Moreover, a previous randomized study by Cattaneo et al[21] with combined use of Damon wires and brackets, but narrower wires with active self-ligating brackets, reported similar levels of first premolar expansion with mean values of 4.5 and 4.3 mm in the active and passive groups, respectively. Slightly greater amounts of intermolar (0.9 mm) and intersecond premolar expansion (0.7 mm) were noted with the Damon system, however, suggesting that any effect of the broadened archwire might be exerted farther posteriorly.[21]

The magnitude of intermolar expansion was relatively minor, peaking at 1.81 mm in the active self-ligation group; the inclination changes reported were correspondingly small, with buccal flaring not exceeding 2.1° in any group. This degree of tipping was less than that reported by Franchi et al[19] and is likely to reflect progression into rectangular steel wires with less torque play, whereas that study did not involve wire advancement beyond round 0.016-in nickel-titanium wires. Cattaneo et al[21] reported significant buccal flaring of premolars (11.7°-13.5°) in their investigation using cone-beam computed tomography scanning, although these changes occurred in conjunction with significant transverse changes. It is, therefore, likely that the interpremolar changes reported in our study were predominantly a result of buccal flaring rather than bodily movement and alveolar remodeling. Cone-beam computed tomography analyses were initially planned in this study to assess maxillary first molar inclination changes and alveolar bone remodeling; however, these were not undertaken after interim data analysis suggested the magnitude of transverse changes to be limited.

A Damon wire sequence was used with all 3 brackets systems in this study. Although the applicability of this treatment protocol could be contested since Damon brackets are rarely used with conventional brackets, we thought that this approach would lead to the most robust comparison of the passive self-ligating bracket with alternatives. Thus, the confounding effects of differences between archwire materials and form could be discounted. The conclusion can therefore be made that this study is a detailed and unbiased assessment of the effects of ligation mode on arch dimensional changes.

Our study was confined to an adult population because we believed that this approach would limit the effects of growth on arch dimensional changes and inclination changes. Carter and McNamara[22] reported mean annual changes of 0.025 mm in subjects from 17 to 48 years; similarly, little change in the inclination of the maxillary teeth can be expected after age 16 years.[23] Consequently, the requirement for an untreated control group was obviated; we also thought that depriving adolescents of necessary treatment would be difficult to justify from an ethical perspective. The changes reported are therefore attributable to the appliances in isolation, negating confounding effects of growth and maturation. Referral patterns and acceptance criteria dictated that many older patients seen in a hospital setting are accepted for treatment in preparation for combined orthodontic-surgical treatment; hence, a wide variation of malocclusions with a relatively high proportion of Class III patients was encountered in this study. Consequently, the results might represent a wide range of orthodontic discrepancies, although further research is required to prove this.

There are undeniable benefits associated with the use of self-ligating brackets; indeed, the authors continue to use these appliances. However, on the basis of this research, resorting to these appliances in the expectation of sculpting unique arch form changes is ill-advised. Treatment planning and extraction decisions rest with the trained clinician and should be predicated on the patient's malocclusion rather than the armamentarium at the clinician's disposal. Manipulation of a self-ligating orthodontic appliance in a crowded arch might be mechanically simple and less cumbersome; however, on the basis of this research, relying on a bracket type to produce "physiologically mediated" arch form changes warranting nonextraction treatment is unfounded.

CONCLUSIONS

In this randomized controlled trial, no differences in maxillary arch dimensional changes or molar and incisor inclination changes were found after alignment with passive self-ligating brackets, active self-ligation, or conventional brackets.

We thank the manufacturers for supplying the brackets and archwires used in the study. The authors are grateful to Tom McDonald, Spencer Nute, Brijesh Patel, Andrew DiBiase, Hayley Stout, Bhavin Soneji, and Paroo Mistry, who between them treated 21 of the patients in this study. We are also grateful to Nikolaos Pandis for providing statistical advice.

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APPENDIX 2. MEDLINE search via OVID (1946 to January 2013)

1 RANDOMIZED CONTROLLED TRIAL.pt. (337494)
2 CONTROLLED CLINICAL TRIAL.pt. (84936)
3 RANDOM ALLOCATION.sh. (75780)
4 DOUBLE BLIND METHOD.sh. (116935)
5 SINGLE BLIND METHOD.sh. (16824)
6 or/1-5 (491890)
7 (ANIMALS not HUMANS).sh. (3653833)
8 6 not 7 (449035)
9 CLINICAL TRIAL.pt. (472733)
10 exp Clinical Trial/ (695959)
11 (clin$ adj25 trial$).ti,ab. (229159)
12 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab. (122976)
13 PLACEBOS.sh. (31132)
14 placebo$.ti,ab. (144395)
15 random$.ti,ab. (621440)
16 RESEARCH DESIGN.sh. (71892)
17 or/9-16 (1268326)
18 17 not 7 (1173804)
19 18 not 8 (740448)
20 8 or 19 (1189483)
21 exp ORTHODONTICS/ (41355)
22 orthod$.mp. (47060)
23 21 or 22 (53516)
24 (bracket$ or brace$ or appliance$).mp. (33063)
25 (self ligat$ or ligat$ or low friction$).mp. (74392)
26 24 and 23 and 25 (491)
27 26 and 20 (84)

APPENDIX 3. Ethical committee approval for the randomised controlled trial.

Cambridgeshire 1 Research Ethics Committee
Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Telephone: 01223 597653
Facsimile: 01223 597645
16 June 2009

Prof Robert Lee - Professor Department of Orthodontics
Bart's and the London NHS Trust
Royal London Dental School
Whitechapel
London E1 1BB

Dear Prof Lee

Study Title:
A randomised clinical trial of orthodontic treatment with 3 fixed appliance systems.
REC reference number:
09/H0304/45
Protocol number:
Version 1
EudraCT number:
N/A

Thank you for your letter of 05 June 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

Notice of no objection must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming no objection or giving grounds for objection, as soon as this is available.

Other conditions specified by the REC –

- On both of the participant information sheets, in the third paragraph: 'prinicipal' needs correcting to 'principal'.
- Confirmation from the R & D Department at the East Kent Hospitals NHS Trust of their approval is required.

Revised version numbers and dates of documents should be provided

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document
Version
Date
Covering Letter from Dr Padhraig Fleming, Senior Registrar in Orthodontics

21 April 2009
Application
Lock code: 15080/35599/1/295
15 April 2009
CV of Ama Johal, Senior Lecturer/Consultant

21 April 2009
CV of Padhraig Fleming, Senior Registrar in Orthodontics

21 April 2009
Investigator CV Professor Robert Lee (academic supervisor)

21 April 2009
GP/Consultant Information Sheets - letter to GP
Version 1
07 April 2009
Protocol
Version 1
07 April 2009
Letter from funder - Professor Robert T Lee, Professor and Head of Orthodontic Department

21 April 2009
Compensation Arrangements letter from Gerry Leonard, Head of Research Resources at Barts and The London

21 April 2009
Statistician Comments letter from Dr Sharif Islam, Lecturer, Dental Public Health at Barts and The London

18 March 2009
Peer Review by Mark Hector

30 March 2009
Letter from Sponsor letter from Mr Gerry Leonard, Head of Research Resources at Barts and The London

21 April 2009
Summary/Synopsis - flowchart of the protocol in non-technical language

07 April 2009
Data Protection Act Research Form

09 April 2009
Questionnaire: (10 questions)
Version 1
07 April 2009
Questionnaire: Discomfort Questionnaire
Version 1
07 April 2009
Questionnaire: Orthognathic Quality of Life Questionnaire
Version 1
07 April 2009

Questionnaire: Oral Health Impact Profile.
Version 1
07 April 2009
CV of Andrew DiBiase - Principal Investigator at Kent & Canterbury Hospital

May 2009
Email correspondence re East Kent Hospitals NHS Trust R&D approval

02 June 2009
Response to Request for Further Information letter from Dr Padhraig Fleming

05 June 2009
Participant Consent Form: Kent & Canterbury Hospital
Version 2
03 June 2009
Participant Consent Form: Bart's and The London
Version 2
03 June 2009
Participant Information Sheet: Kent & Canterbury Hospital
Version 2
03 June 2009
Participant Information Sheet: Bart's and The London
Version 2
03 June 2009

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0304/45
Please quote this number on all correspondence

Yours sincerely

Dr Daryl Rees
Chair

Email: susan.davies@eoe.nhs.uk

Enclosures:
"After ethical review – guidance for researchers"

Copy to:
Dr Gerry Leonard
Research and Development
Barts and The London
24-26 Walden Street
Whitechapel
London E1 2AN

APPENDIX 4. Information leaflet: Barts and The London School of Medicine and Dentistry.

Bart's and The London Queen Mary's School of Medicine and Dentistry

PARTICIPANTS INFORMATION SHEET

(Version 2. Date: 03.06.09)

A randomised clinical trial of orthodontic treatment with 3 fixed appliance systems.

Invitation
We invite you to take part in a research study which we think may be important. Before you decide it is essential you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study and why have I been chosen?
We are interested in assessing the effects of different fixed orthodontic braces ('train tracks') on the quality and speed of orthodontic treatment. In addition, we would like to find out how our patients feel about these different appliances.

This study will be led by the principal investigator, Dr Padhraig Fleming (BDentSc. (Hons.), MSc., MFDS RCS, MFD RCS, MOrth RCS), Senior Registrar in Orthodontics.

You have been selected to participate in this new research as you will shortly be receiving fixed braces in preparation for orthognathic surgery. The results of the research will be made available to you following completion of the study.

Do I have to take part?
No, it's up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign the consent form. You are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you withdraw from the study, we will need to use the data collected up to your withdrawal.

What will happen to me if I take part?
If you agree to take part, the researchers will randomly allocate you to be

treated with one of 3 different fixed braces. You will then have one of 3 braces placed as part of your treatment. You will be asked to complete 3 questionnaires during the study and your orthodontist will need to take an extra mould of your teeth during treatment. Otherwise, your treatment will be no different from any patient in our department. You will be involved in the study for a total of 12 months. No payments or expenses will be paid if you participate in the research study.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of research will be kept strictly confidential. If you consent to take part in the research the people conducting the study will abide by the Data Protection Act 1998, and the rights you have under the Act. We will keep the data collected for the investigation separate from your hospital records and store the data for a period of 5 years.

Access to personal data will only be available to the principal researcher and treating clinicians. There will be no access to the information by individuals outside the health team. All your personal data will be processed and stored securely in compliance with the Data Protection Act 1998.

Involvement of the General Practitioner/ Family doctor (GP).
With your permission, a letter will be sent to your GP (General Practitioner) to let them know about you participation in the study.

What are the other possible disadvantages and risks of taking part?
There are no additional disadvantages or risks of taking part in this study.

What happens if you are worried or if there is an emergency?
You will always be able to contact an investigator to discuss your concerns and/or to get help:

Dr Padhraig Fleming
The Royal London Hospital,
Orthodontic Department,
Institute of Dentistry,
New Road
Whitechapel
London E1 1BB.

Tel 020 7377 7397

What happens if there is a problem?
Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of

the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

Please contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you received, or as an initial point of contact if you have a complaint. Please telephone 020 7377 6335, minicom 020 7943 1350, or email pals@bartsandthelondon.nhs.uk, you can also visit PALS by asking any hospital reception.

Research Ethics Committee.

For your information the study has been reviewed by the Cambridgeshire1 Research Ethics Committee as part of the National Research Ethics Service.

APPENDIX 5. Consent form: Barts and The London School of Medicine and Dentistry.

Participants Written Consent Form
Bart's and The London
Queen Mary's School of Medicine and Dentistry

<u>Version 2: 03/06/2009</u>

A randomised controlled trial of orthodontic treatment with 3 fixed appliance systems.

Name of Participant: ______________________________________
Please initial box to indicate agreement

- The study organisers have invited me to take part in this research. ☐
- I understand what is in the leaflet about the research. I have a copy of the leaflet to keep. ☐
- I have had the chance to talk and ask questions about the study. ☐
- I know what my part will be in the study and I know how long it will take. ☐
- I have been told about any special operations, tests or other checks I might be given. ☐
- I know how the study may affect me. I have been told if there are possible risks. ☐
- I understand that I should not actively take part in more than one research study at a time. ☐
- I know that the Cambridgeshire1 Research Ethics Committee has seen and agreed to this study. ☐
- I understand that personal information is strictly confidential: I know the only people who may see information about my part in the study are the research team. I understand that my personal data will be processed and stored securely in compliance with the Data Protection Act 1998. ☐
- I know that the researchers will tell my GP about my part in the study. ☐
- I freely consent to be a subject in the study. No one has put pressure on me. ☐
- I know that I can stop taking part in the study at any time without giving any reason. ☐
- I know if I do not take part, or if I drop out of the study I will still be able to continue to have my treatment as normal. ☐
- I know that if there are any problems, I can contact the investigators. ☐

Participant's Signature: ______________________________________

Date: ______________________________________

The Clinicians/Investigators responsible for obtaining consent should sign the following.

As the Clinicians/Investigators responsible for this research or a designated deputy, I confirm that

I have explained to the participant / volunteer named above the nature and purpose of the research to be undertaken.

Clinician's Name:

____

Clinician's Signature: ______________________________________

Date: ______________________________________